



36

Mr. LIVINGSTON. I just wanted to assure the gentleman that it is my intention that not only our joint leadership, but that the gentleman and I and the respective subcommittee chairmen from both the majority and the ranking minority members have full opportunity to review all proposals before they hit the floor and that the staff has adequate time to read it and make sure that mistakes are not made.

The fact is that the committees are working, and especially, I think, the Committee on Appropriations in this instance is working as expeditiously and efficiently as is absolutely possible under rather uncertain conditions, and I am proud of the job we are doing. I am just not able to give the gentleman any guarantees about the ultimate schedule.

Mr. ROGERS. Mr. Speaker, will the gentleman yield?

Mr. OBEY. Again, further reserving the right to object, Mr. Speaker, I yield to the gentleman.

Mr. ROGERS. Mr. Speaker, the gentleman from Wisconsin and the chairman of the committee is correct. Just on the Commerce-State-Justice bill it will take 12 or 13 hours of staff time just to read through, to proofread, that one bill.

□ 1945

So we need a lot of lead time. We have been trying to pre-read the portions that are more or less agreed to. But even in spite of that, it is going to take that long a period of time, just to read on the one bill.

Mr. OBEY. Mr. Speaker, continuing my reservation, let me simply make this point, I think we have terrific staff on the Committee on Appropriations. But as good as they are, they are likely to make some significant mistakes if they are reading out these bills when they have been strung out through night after night with virtually no rest.

It seems to me that if there is not a reasonable expectation that we can finish, that we ought to recognize that so that Members can get some sleep. My observation is that this place usually works better and the Members get along better with each other when their tails are not dragging, and everybody's are, as far as I can see right now, and certainly the staff.

Mr. Speaker, we are not going to get any more information, but what we have been told so far is that the fast-track legislation is going to come up sometime tonight, that we may or may not be moving ahead with other appropriation bills, and, if we do move ahead with them, they may or may not be in an omnibus form, and we do not really have any idea at this point how long it is going to take to read out these bills or to bring them to the Congress in a form which is safe for Members to vote on.

Under those circumstances, I would simply say I am dubious that a one-day CR is going to solve anything.

Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Louisiana?

There was no objection.

The text of House Joint Resolution 104 is as follows:

H.J. RES. 104

*Resolved by the Senate and House of Representatives of the United States of America in Congress assembled.* That section 106(3) of Public Law 105-46 is further amended by striking "November 9, 1997" and inserting in lieu thereof "November 10, 1997", and each provision amended by sections 122 and 123 of such public law shall be applied as if "November 10, 1997" was substituted for "October 23, 1997".

The SPEAKER pro tempore (Mr. PETRI). Without objection, the joint resolution is considered and passed.

There was no objection.

A motion to reconsider was laid on the table.

#### CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY. Mr. Speaker, I move to suspend the rules and agree to the conference report on the Senate bill (S. 830) to amend the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

(For conference report and statement, see prior proceedings of the House of today.)

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL] each will control 20 minutes.

The Chair recognizes the gentleman from Virginia [Mr. BLILEY].

GENERAL LEAVE

Mr. BLILEY. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous remarks on the conference report on S. 830.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Virginia?

There was no objection.

Mr. BLILEY. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today we stand on the verge of medical advances that will revolutionize the quality of health care in America, and today we make the promise of better medicines and treatments a reality for millions of Americans. The bipartisan conference agreement reached earlier this afternoon to modernize the FDA is a victory for American patients.

After almost 3 years of work by the Committee on Commerce, we have delivered a piece of legislation that will do more to help patients than any legislation passed in decades. When we first discussed the need to modernize the FDA in 1995, we knew that outdated rules were slowing down the vital work of the agency and that patients

were the ones who were suffering. Vital new medicines and medical devices were not getting to the patients who needed them quickly enough.

As I said back then, it is not right that American patients are having to go overseas to get the care they need to stay alive. Congress had to act. Our FDA reform team conducted the most extensive legislative outreach in recent memory. Literally thousands of hours were devoted to reaching out to all corners of the country. Our goal then was to achieve a balanced legislation, legislation that the President would be eager to sign.

Today we have fulfilled our objectives. This agreement will result in a better and more efficient FDA. It will enhance the safety of the medicines we take and the medical devices we use and the foods we feed our children. Medicines will be approved faster, medical devices will get to people sooner, and those with life-threatening diseases will have access to the best experimental new drugs that science can provide. That is important, because when you are sick, when you are suffering, every minute counts.

Some of my colleagues deserve special praise and thanks. Their work on this issue has been tireless, and the credit for this legislation belongs to them. The members of our FDA reform team, the chairman of our Subcommittee on Health and Environment, the gentleman from Florida [Mr. BILIRAKIS], along with the gentleman from Pennsylvania [Mr. GREENWOOD], the gentleman from North Carolina [Mr. BURR], the gentleman from Texas [Mr. BARTON], and the gentleman from Kentucky [Mr. WHITFIELD].

I also want to reach across the aisle to thank our friends, the gentlewoman from California [Ms. ESHOO], the gentleman from New York [Mr. TOWNS], and the gentleman from Texas [Mr. HALL], and all our ranking members, the gentleman from Michigan [Mr. DINGELL] and the gentleman from Ohio [Mr. BROWN], for their invaluable contributions to this effort. And to our colleagues over in the Senate, Senators JEFFORDS and KENNEDY.

I also want to thank my committee staff, Howard Cohen, Eric Berger, and Roger Currie, as well as the personal staffs of the FDA reform team, Patti DeLoache with the gentleman from Florida [Mr. BILIRAKIS], Mora Guarducci with the gentleman from Pennsylvania [Mr. GREENWOOD], Alyson Neuman with the gentleman from North Carolina [Mr. BURR], Beth Hall with the gentleman from Texas [Mr. BARTON], Pete Bizzozero with the gentleman from Wisconsin [Mr. KLUG], and Tim Taylor with the gentleman from Kentucky [Mr. WHITFIELD].

I would also like to extend my gratitude to the able and hard-working legislative counsels who helped craft this measure: David Meade, Pete Goodloe, and Liz Aldridge.

Finally, I would like to express my sincere gratitude for the hard work and dedication of minority counsel Kay Holcombe. She is leaving us at the end of this session, and, believe me, she will be greatly missed, not just by the gentleman from Michigan [Mr. DINGELL] but by this chairman as well.

They should all be proud of a job very well done. The American people thank them, and so do I.

Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I yield myself 4 minutes.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Mr. Speaker, from the beginning, our goal in reforming Food and Drug has been to benefit patients and people. We can talk about a lot of things, but when we get right down to it, the question is keeping people safe, seeing to it that foods, drugs, cosmetics, devices and other things which are regulated by Food and Drug which are absolutely essential to the life of people are safe and that they come quickly to market.

The bill does a number of things. First, it reauthorizes the Prescription Drug User Fee Act. This is a program that has given FDA the resources needed to approve drugs in a way that none of us would have anticipated 10 years ago. Today, new drugs are reviewed by FDA in a year or less. Drugs essential for people with serious and life-threatening illnesses are reviewed in 6 months or less. This is enormous progress.

The bill authorizes a clinical trials bank that would be established through the National Library of Medicine at NIH. Patients with serious illnesses will be able to get critical information about experimental therapies being tested in clinical trials.

The bill codifies a number of procedures that FDA developed over the years to expand access to experimental drugs and medical devices to people with serious illnesses and emergency situations through so-called expanded access protocols.

Market incentives are included in this bill to encourage companies to produce pediatric studies of drugs, so that the labeling of these products will be useful to pediatricians. Today, most of these drugs prescribed for children have no proper pediatric label. The bill remedies this situation. I expect the FDA will use this new authority carefully to avoid detrimental impact on the availability of generic drugs.

The medical device provisions of the legislation have been the most controversial and difficult. I am pleased that the conference report includes provisions based on a careful consideration of two goals: Expediting the availability of new, sophisticated products; and protecting patients from medical devices that are either unsafe or ineffective.

The bill gives the FDA the ability to fine its evaluation of medical

devices, but without compromising its ability to make absolutely sure that the products are safe, that they work the way they are supposed to be, and are labeled properly.

I am also pleased the conference report retains two significant provisions from the House bill. One makes certain FDA will not be forced to approve a product the agency knows the manufacturer cannot make according to good manufacturing practices. The second ensures that FDA can evaluate all aspects of a new medical device, not just the ones that the manufacturer chooses to include in the label.

I am concerned, Mr. Speaker, that while we are busy reforming the Food and Drug Administration, we put a number of burdens on the agency and that the potential to interfere with the review and approval of new products is real. I am also concerned that the speed which is required may have an element of risk for the consuming public for patients and for people involved in health care.

Mr. Speaker, I want to commend and thank my good friend and colleague, the gentleman from Virginia [Mr. BLILEY], for his excellent work on this important legislation and for his leadership in what has been a truly bipartisan effort.

In addition, the work of the subcommittee chairman, the gentleman from Florida [Mr. BILIRAKIS], was essential to the success of the effort, as were the labors of the gentlewoman from California [Ms. ESHOO], the gentleman from Texas [Mr. BARTON], the gentleman from California [Mr. WAXMAN], the gentleman from Ohio [Mr. BROWN], the gentleman from Pennsylvania [Mr. KLING], the gentleman from North Carolina [Mr. BURR], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Kentucky [Mr. WHITFIELD].

Our Senate colleagues, Senators JEFFORDS, KENNEDY, and COATS worked very hard.

The staff of the committee, Howard Cohen, Eric Berger, Roger Currie, and the staff of the conferees, Kevin Brennan, Paul Kim, Emmett O'Keefe, Pattie DeLoache, Alyson Neuman, Beth Hall, Mora Guarducci, and Tim Taylor were valuable and important in the accomplishments of this legislation, as were the tireless efforts of David Meade and Peter Goodloe of House Legislative Counsel and Elizabeth Aldrich of Senate Legislative Counsel.

I want to refer to the work done by my dear friend and our valuable staff member, Kay Holcombe, who will be leaving us at the end of this year. Simply put, without her labors, we would not have achieved the consensus FDA bill that we have before us today. It took a great deal of effort on her part, her unquestioned integrity, her considerable intelligence, her extensive expertise, and her legislative tenacity to help us get to the point where we are.

The legislation is a fitting capstone to the labors of all who have partici-

pated, but especially to Kay's distinguished career in public service and her 4 years with the staff of the Democratic part of the committee. Her retirement is a loss to all.

This is a fine piece of legislation. I urge my colleagues to support it.

Mr. BLILEY. Mr. Speaker, I yield 5 minutes to the gentleman from Florida [Mr. BILIRAKIS], the very able chairman of the Subcommittee on Health and Environment of the Committee on Commerce.

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman for yielding me time.

Mr. Speaker, I rise, of course, in support of the conference report. As chairman of the subcommittee of jurisdiction, I believe the conference report represents our best effort in many years to improve the health and safety of all Americans.

In short, this comprehensive law will chart a new course in public protection, allowing the Government to fulfill its obligation to protect the public health without undue delay, while ensuring that we preserve the economic incentives inherent in our free market system. Although it has taken many months, indeed, many years of hard work, this legislation represents a bipartisan effort to work through our political differences and resolve contentious issues.

Over the last 3 years, Mr. Speaker, the Committee on Commerce and my Subcommittee on Health and Environment in particular have produced a number of landmark bills which have enjoyed support from both sides of the aisle.

Last year, for example, the Subcommittee on Health and Environment produced the innovative Food Quality Protection Act and legislation to substantially improve the operation of the Safe Drinking Water Act. In addition, my subcommittee crafted a health insurance portability act to make basic reforms to the health insurance system and worked on the Balanced Budget Act of 1997 to include the new children's health care program and important reforms to the Medicare and Medicaid programs.

□ 2000

We also reauthorized the Ryan White Act, thus authorizing Federal dollars to States for HIV education, prevention and health service programs. I am very proud of these important accomplishments, particularly because they were done in a bipartisan way.

The foundation of the present FDA bill was developed during the last Congress, and from the beginning, our effort has been an open process, open to anyone interested in FDA reform. Our committee conducted 17 separate formal hearings on FDA reform and FDA-related issues. This represents 72 hours, 44 minutes, and 2,094 pages of testimony.

There are many who deserve credit for bringing this legislation to the

floor today, several Committee on Commerce members in particular: The gentleman from Pennsylvania [Mr. GREENWOOD]; the gentleman from North Carolina [Mr. BURR]; the gentleman from Texas [Mr. BARTON]; the gentleman from Wisconsin [Mr. KLUG]; the gentleman from Kentucky [Mr. WHITFIELD]; the gentleman from Ohio [Mr. BROWN]; the gentlewoman from California [Ms. ESHOO]; the gentleman from California [Mr. WAXMAN]; the gentleman from Pennsylvania [Mr. KLINK]; the gentleman from Texas [Mr. HALL]; the gentleman from New York [Mr. TOWNS], along with our personal staffs who have dedicated many long hours to this bill. However, it was the leadership and direction, of course, of the gentleman from Virginia [Mr. BLILEY], our full committee chairman, and the gentleman from Michigan [Mr. DINGELL], our ranking minority member, which enabled us to bring the consensus bill before the House today. At the beginning of this Congress the chairman of the full committee made it clear that he wanted action to FDA legislation and his determination to see this through has been a guiding force in our deliberations.

In addition, the cooperation of both HHS Secretary Donna Shalala and Acting FDA Commissioner Dr. Michael Friedman during this process enabled us to achieve our ultimate goal of creating thoughtful and practical FDA reform legislation which will be signed into law, I trust, by the President this year.

Finally, I want to acknowledge and thank the most important people, the committee staff on both sides of the aisle, for their dedication and hard work in crafting this important legislation, especially Howard Cohen, Kay Holcombe, who is leaving us, and, boy, are we going to miss her; Rodger Currie, Eric Berger, David Meade, Pete Goodloe and Pattie DeLoache of my personal staff.

I am proud of this legislation, Mr. Speaker. It will reduce the overregulation of research-based businesses while greatly improving the lives of millions of Americans. I believe we have done our work and done it well. I urge my colleagues to support this conference.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from Ohio [Mr. BROWN].

Mr. BROWN of Ohio. Mr. Speaker, today the House considers the conference report on the reform of the Food and Drug Administration. The debate on FDA reform progressed from irrational and unfounded accusations about FDA's regulation of medical products to much more rational discussions about how to modify this agency's regulatory policies and procedures in a way that will ease unnecessary regulation without reducing essential protections of public health.

I want to commend the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL], the ranking member, and the

gentleman from Florida [Mr. BILIRAKIS], chairman of the subcommittee, for their diligence in holding the House conferees together on issues that this body believed in. I want to commend the tireless work of our staffs, particularly Kay Holcombe and Howard Cohen.

This was not an easy task, particularly in light of the tremendous differences of opinion about what constitutes "unnecessary regulation." To make the system more accessible to consumers, it was necessary to draw a line between creating reasonable public processes and overburdening the FDA with administrative duties that take time away from the most important functions of getting safe and effective new products to market as quickly as possible.

Many argue that FDA reform is essential, because new and improved products were not reaching American consumers quickly enough. The facts simply did not bear this out. The FDA's Center for Devices literally overhauled its operations and dramatically improved its review time for new products. We reached a compromise where critics of this process and the medical device industry can be comfortable.

Perhaps the most important provision included in this legislation is the reauthorization of the Prescription Drug User Fee program. This program has provided the resources that FDA needed to make it the world leader in the review and approval of new drugs. If there were one single reason for Congress to pass this bill today, drug user fees is that reason.

Some of us may not be completely satisfied with the reforms of FDA regulation of generic drugs. I believe, however, that the debate led to some very much needed improvements. While these products are not the so-called miracle drugs we read about in headlines, generic drugs are critically important, because they provide options for physicians and for patients that often are less expensive than brand name products. Generic drugs literally save billions of dollars in health care costs, much of those savings occurring to the Federal Government through Medicaid, Veterans and Department of Defense facilities. In addition, savings in drug costs are important especially for senior citizens who obviously purchase the largest percentage of prescription drugs.

Mr. Speaker, I was especially pleased that a number of issues raised by Democratic members of the subcommittee, chaired by the gentleman from Florida [Mr. BILIRAKIS], were addressed in this legislation. I appreciate the willingness of the bill's sponsors, the gentleman from Virginia [Mr. BLILEY] and the gentleman from Florida [Mr. BILIRAKIS], to engage in these negotiations, and they were able to hold the House position during this conference.

Mr. Speaker, FDA is a remarkably effective agency. I have never been per-

suaded that massive changes in law were needed to correct some dreadful problem lurking under the surface.

I ask my colleagues to pass the conference report.

Mr. BLILEY. Mr. Speaker, I yield 2 minutes to the gentleman from North Carolina [Mr. BURR].

Mr. BURR of North Carolina. Mr. Speaker, I thank the gentleman for yielding me this time.

Mr. Speaker, today we take a historic step towards the future of health care in America. Today we will vote on the conference report for the Food and Drug Administration modernization legislation, originally H.R. 1411 in the House, and now S. 830.

FDA modernization is not radical, it is responsible. It is not senseless, it is safe. For thousands of patients and their families, the FDA has become a cold, inhuman and indifferent bureaucracy with a lagging drug and medical approval process and a culture of unresponsiveness and disconnect. The FDA has become an obstacle in some American families in the hope for new treatments. The FDA, regulating 25 cents of every dollar in the U.S. economy, affects every American family.

This legislation will prepare the agency for technology and medical breakthroughs for the 21st century. This legislation provides hope from the corner store pharmacist who wants to provide the best medication possible to his customers, to the hospital passionately fighting against an outbreak of an antibiotic-resistant bacteria strain, to the rural doctor who desperately seeks medication to treat patients, to the terminally ill cancer patient who has no medical option left in the struggle against a devastating disease.

This legislation in fact puts a human face on the Food and Drug Administration. By infusing common business sense into the daily operation of FDA, we will enable the agency to approve safe drugs more efficiently and to reduce skyrocketing costs of research and development that is bogged down in bureaucratic red tape.

I want to thank the gentleman from Virginia [Mr. BLILEY], the chairman of the committee, Chairman JEFFORDS in the Senate, the gentleman from Florida [Mr. BILIRAKIS], the gentleman from Michigan [Mr. DINGELL], the FDA Reform Task Force, the committee staff, my staff and the Senate staff who literally spent hundreds of hours working on this very important legislation that I believe deserves the support of our entire House membership.

Today we celebrate hope and life. This legislation would not be possible without hundreds of patients who brought their personal stories to Washington. Unfortunately, many of those patients did not live to see this day.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from California [Ms. ESHOO].

Ms. ESHOO. Mr. Speaker, I thank the gentleman from Michigan [Mr. DINGELL] for yielding me this time.

This evening I rise in strong support of the conference report, and I urge my colleagues to support it as well. Let me start out by acknowledging the leadership, and without the leadership of the gentleman from Virginia [Mr. BLILEY], our committee chairman, the gentleman from Florida [Mr. BILIRAKIS], our subcommittee chairman, and certainly the gentleman from Michigan [Mr. DINGELL], our ranking member, and the gentleman from Ohio [Mr. BROWN] of the subcommittee, and all of the Members from my side of the aisle as well as the majority, we would not come to this moment.

Like all conference reports, it represents a compromise. Nonetheless, the agreement is entirely consistent with the bill which passed the House by a voice vote last month. That is highly unusual for a bill of such substance and such importance to come to the floor and be passed by a voice vote. I am proud of the role that I was able to play in this.

The FDA, I believe, will be a better agency because of this legislation. Drugs and medical devices will get to patients sooner without any reduction in the safety and the effectiveness of these products.

I am particularly pleased that a compromise was reached among the conferees on a provision allowing for accredited third parties to review medical devices, and that the House held its position with regard to the labeling of devices. Had the House not insisted on language, this conference report would have been vetoed, and all of our hard work would have been lost.

I hope, Mr. Speaker, that my colleagues appreciate the tremendous bipartisan, bicameral support that went into bringing this conference report to the House today. The list of people to thank is far too long to mention here, but there is one, because I think if there were a subset title to this bill, it would be the Kay Holcombe Act of 1997. The tributes that have been paid to her are well-deserved and she should receive the gratitude and the applause of the American people, because they are the ones that we really went to the table for, and were it not for her professionalism, her patience, her hard work, we would not have arrived at this moment.

I salute everyone that was a part of this, and if there is anyone on either side of the aisle that thinks that there are not unending opportunities to seize in the Congress, they are wrong. I found one with my colleagues, and one of them seated on the other side of the aisle, JOE BARTON, my partner on the medical device bill, many thought that with the two of us being partners that it could not be done. It was done, we come to this moment, and I urge my colleagues to support the conference report. It is good for the American people and we are proud of the effort.

BLILEY. Mr. Speaker, I yield 2 minutes to the gentleman from Texas [Mr. BARTON].

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. Mr. Speaker, I thank the gentleman from Virginia for yielding me this time.

Mr. Speaker, most of us go through life being blessed with good health for ourselves and our loved ones, but as Members of Congress, we have all been literally begged by parents of sick children and our very ill adult patients themselves to try to help them work through the regulatory nightmare that is the current FDA review process.

When the bill before us becomes law, that nightmare will be no more. Instead of confrontation, we will have consultation and cooperation between the FDA, patient groups, researchers, and manufacturers. Instead of needless bureaucracy, we will have streamlined procedures for bringing the most comprehensive new medical devices and drugs to market as soon as is safely possible.

In the medical device section of the bill that the gentlewoman from California [Ms. ESHOO] and I cosponsored together in the House, we have a very practical third-party review process, we have a dispute resolution procedure that will allow researchers and manufacturers to work out their differences with the FDA reviewers; we have a reclassification of the existing device section that will let a lot of devices that are now class 3 be class 1 or class 2. Very importantly, we have an expanded and reformed use for humanitarian medical devices that will bring some of these experimental devices as quickly as possible to the market.

I must thank the gentlewoman from California [Ms. ESHOO], who has just been a one-man band in trying to force compromise and get me to back down when I really did not want to. She has done excellent in that. The staff level, in addition to the other staffers, I would like to thank Bill Bates of the office of the gentlewoman from California [Ms. ESHOO], Alan Sloboddin of the committee oversight staff, and Beth Hall of my staff, who have all done yeoman's work.

This is not a perfect bill, but it is a great start. I am going to use the oversight chairmanship to oversee implementation, and I hope that we pass this unanimously this evening. It is good for the American public.

□ 2015

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the gentleman from California [Mr. WAXMAN].

Mr. WAXMAN. Mr. Speaker, my congratulations to the gentleman from Virginia, Chairman BLILEY, and the gentleman from Florida, Mr. BILIRAKIS, and our Democratic leaders, the gentleman from Michigan, Mr. DINGELL, and the gentleman from Ohio, Mr. SHERROD BROWN, for producing the Food and Drug Administration Modernization Act, which marks the successful end of a long 3-year process. I

do not agree with some of the provisions in this bill, and I certainly would have written it differently, but I do support it today.

I have no difficulty in supporting this legislation in large part because Chairman BLILEY developed a process where all Members could participate, their views could be heard, and compromises could be reached. That kind of leadership is harder than some might think, because there is always pressure to be partisan and to get what one side and only one side wants. But if we are going to ever pass legislation into law, we have to recognize that it needs to be done on a bipartisan basis, and we have to have a process where we try to find common ground.

I want to express my appreciation to our chairman for his leadership. I do have some reservations about the scope of many of the provisions in this legislation, particularly when it comes to the off-label promotion of drug and devices and third-party review of devices. But I want to point out that these are experimental provisions with sunsets which will allow us to critically reexamine their public health consequences.

I applaud very strongly the reauthorization of the Prescription Drug User Fee Act, which I was proud to have authored. It has been very successful and has allowed the FDA to speed the approval of drugs.

There are a number of other provisions that we ought to take note of because they will directly benefit many patients. The requirement that drug companies report on their fulfillment of postmarketing studies fills an important gap in ensuring that critical information is reaching patients. The clinical data base will create new opportunities for patients to have greater access to comprehensive information about experimental therapies for serious and life-threatening diseases. It is my expectation that companies will work with the FDA in this enterprise in the same cooperative spirit in which it is enacted.

The pediatric drug provision complements the FDA's recent regulations, and provides targeted incentives to improve the quality of health care for infants and children. Although I had reservations regarding the need to provide additional market exclusivity following the proposal of the regulations, there may still be limited situations in which this provision will encourage new clinical research to establish the safety and effectiveness of drugs for children.

The provision requiring notice of discontinuance of the manufacture of life-saving drugs will ensure that patients receive time to find alternatives to medicines which will no longer be available. Instead of having to make medically sensitive decisions in haste, they will have 6 month's notice of a company's decision which could have tremendous implications for their health. Only a company with "good

cause" will be permitted to end distribution or manufacture of its drug with less than 6 months notice, and in that event, the FDA will be able to determine the accuracy of this claim through records and documentation.

The preemption of state laws regarding over-the-counter drugs and cosmetics has been resolved in an important compromise, under which the FDA is granted new enforcement authority over OTC drugs, the states are not preempted with respect to cosmetic safety, and preemption of cosmetic packaging and labeling only occurs where the FDA has taken action on specific and narrow questions. Most importantly, this provision does nothing to affect California's Proposition 65, an innovative state initiative that has helped reduce Californians' exposure to toxic hazards.

This bill is a far cry from the proposals first floated three years ago which ran roughshod over consumer protections, supplanted our own product approvals with those of other countries, and weakened crucial statutory guarantees of safety, effectiveness and quality. The reason for this striking difference was the persistent skepticism of American consumers, who understood that it is the FDA which ensures that our food is safe and our medicines are safe and effective.

This was made clear by the Patients' Coalition, which represents a hundred patient and consumer organizations and hundreds of thousands of patients. For three years, the Coalition has vigorously opposed extreme and controversial proposals for FDA deregulation. Today, this bill will receive bipartisan support because of the Coalition's unremitting vigilance and hard work in defeating efforts to weaken public health protections through FDA "reforms."

Given the extraordinary success of PDUFA, it makes sense for Congress to apply user fees to other areas of FDA jurisdiction, including medical devices. Enacting such fees, modeled on authorized, additive user fees under PDUFA and not upon the unauthorized "sham" fees frequently proposed by OMB, would bring similar efficiencies to the device approval process.

Regrettably, this legislation does not do so. Instead, it enacts substantial new burdens on the FDA and, in particular, the Center for Devices and Radiological Health. I am deeply concerned that unrealistic deadlines and dozens of new mandates will slow the tremendous progress that has been made in speeding device approvals. It remains to be seen whether we will inadvertently divert limited staff, time and resources from the FDA's most important business—ensuring that our food supply is the safest in the world and that drugs and devices are safe and effective.

I want to recognize the important work of the staffs on both sides of the aisle in developing this legislation. Without them it would have been im-

possible for us. I want to compliment as well those in the Senate who played such an active role, and all of my colleagues who have played an important role, in developing this legislation.

I especially want to recognize the dedication and hard work of Kay Holcombe, our Commerce Committee staff, and the work of Howard Cohen, Eric Berger and Rodger Currie, the Majority committee staff, on this legislation. I would also emphasize the tireless work by the professionals at the FDA, including Bill Schultz, Peggy Dotzell and Diane Thompson, and the representatives of the Patients Coalition, Scott Sanders, Michael Langen, Maura Kealey and Tim Westmoreland.

I complement Chairman BLILEY and Congressman DINGELL of the Commerce Committee, and Chairman JEFFORDS and Senator KENNEDY of the Senate Labor and Human Resources Committee, for their hard work and join my colleagues in supporting this important legislation.

Mr. BLILEY. Mr. Speaker, I yield myself 15 seconds.

Mr. Speaker, I just want to thank the very kind and generous remarks of the gentleman from California [Mr. WAXMAN]. I hope that not too many of my people down in Richmond were watching. It might have an adverse affect on me in the next election. But again, I thank him very much, and I have enjoyed working with him.

Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania [Mr. GREENWOOD], whose work played a great part in bringing this legislation to us this evening.

Mr. GREENWOOD. I thank the chairman for yielding, Mr. Speaker, and I thank him also for the opportunity to chair this task force.

When Chairman BLILEY asked me to chair the task force on the FDA reform, I did not know a whole lot about the FDA, not more than most people did, but I learned an awful lot. One of the things that I learned is that we are approaching what I think will be a golden age of medicine. We are making such incredible breakthroughs right now in biotechnology and genetic engineering, in pharmacology, in the development of high-tech medical devices, that I believe that we are going to give the next generation in the next century, as well as many of us, opportunities to defeat diseases that have plagued mankind for a very long time, and be able to relieve people from their suffering from these diseases.

But central to this promise is the role of the Food and Drug Administration. The Food and Drug Administration exists for the very critical job of making certain that all of these miracle cures, all of these devices and drugs, are both safe and effective.

The problem we discovered is that the agency had become bureaucratic, and the law that governs it had become antiquated and was not keeping up with this modern age of miracle cures. We set about the role of seeing if we

could make the FDA work more efficiently, bring these cures to those who are suffering more rapidly, while still maintaining the golden standard of safety and efficacy.

I also learned of some very human situations. I learned that I had a constituent whose name is Shelbie Oppenheimer. She is a hero to me. She is a 30-year-old woman who at the age of 28 was running a day care center and discovered that she had ALS, Lou Gehrig's disease. It is a progressive, fatal neuromuscular disorder that attacks nerve cells and pathways in the brain and spinal cord.

There is no cure for it, but there is a new medication that can delay the onset of the disease and slow its progress. My constituent, Shelbie Oppenheimer, and her husband, Jeff Oppenheimer, desperately want her to have access to this medication. Mr. Speaker, it is my hope that this legislation gives Shelbie Oppenheimer the extra time and the extra hope that this new medication will provide her.

I would like, Mr. Speaker, to dedicate this bill to Shelbie Oppenheimer and to all of the other Shelbie Oppenheimers around the country who are waiting for the Congress to reengineer the FDA so that it can approve these new miracle cures for them more rapidly.

I am also pleased that the legislation that I had introduced separately, the better pharmaceuticals for children bill, has been incorporated into this reform package, so we can bring the miracles of modern medicine not only to adults, but to the children who up until this time were not the subject of trials.

I would like to thank all of my colleagues and the chairman, the gentleman from North Carolina [Mr. BURR], the gentleman from Texas [Mr. BARTON], the gentleman from Wisconsin [Mr. KLUG], and the gentleman from Kentucky [Mr. WHITFIELD], for their assistance, and certainly echo the comments of those who have praised our very, very able staff.

Mr. DINGELL. Mr. Speaker, I yield 3 minutes to the distinguished gentleman from New Jersey [Mr. PALLONE].

Mr. PALLONE. Mr. Speaker, the conference report before us has been the product of hard work, tough negotiations, and true bipartisanship. The result is a well-crafted bill that will reauthorize the Prescription Drug User Fee Act, and enact common-sense Food and Drug Administration reform.

I want to congratulate the chairman and the ranking member and the professional staff of the committee on both sides of the aisle, particularly Kay Holcombe, for their work on this very successful piece of legislation.

Pursuant to the bill, patients will have access to safe new drugs, treatment, and equipment faster than before; businesses will be able to save their customers money without sacrificing safety; and the FDA will be able to focus more time and money on regulating medical treatments instead



of pushing paper. I think it is a win for everyone.

Mr. Speaker, I just wanted to mention a few provisions of the bill that I am particularly concerned with, concerning the drug provisions. I am particularly pleased with the inclusion of a bipartisan amendment that would provide for notification when a company terminates a product which could cause severe harm to a patient because of its discontinuance.

To allay industry concerns, I ask that there would be included in the bill a good cause waiver that allows the FDA to waive the time requirement. I understand that the provision has been slightly modified in conference in that companies have to certify to the FDA that these good cause waiver requirements are met. This provision still represents good citizenship by the sole manufacturers of medical products, and I believe that the conference report compromise is a good one.

In addition, two amendments concerning mercury were incorporated into this bill. One of them requires the FDA to restudy the impact of a form of organic mercury in nasal sprays on the brain, and the second provision provides for a study that would examine the sale of mercury as a drug or for other home use. These are both good government provisions. I appreciate the work of the committee for including them in the conference report.

On the device side, I wanted to congratulate the gentlewoman from California [Ms. ESHOO] and the gentleman from Texas [Mr. BARTON] for their ability to find common ground with the FDA and the industry on many issues. While third-party review may not be the panacea, freeing up the FDA's limited resources to review and approve high-risk devices is the next best thing, especially without greater resources being devoted to the FDA directly.

Finally, I am very pleased that language was included, the House language, to ensure that this legislation does not hinder the FDA's authority to reduce teen smoking. We are going to be dealing with the issue of teen smoking and tobacco in general in the committee. I know we are going to start having hearings on it next week. I think it was important and sound policy that this provision be included.

I just want to urge adoption of this conference report. I know that the committee and the staff and all have worked very hard on this. I think it is a very successful bill that will be passed into law and signed by the President.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Florida [Mr. STEARNS], a member of the committee.

(Mr. STEARNS asked and was given permission to revise and extend his remarks.)

Mr. STEARNS. Mr. Speaker, I am to support the FDA reform bill, to compliment the chairman and ranking member, and, of course, the

subcommittee chairman, the gentleman from Florida [Mr. BLIRAKIS], who is a colleague. But I am disappointed that this legislation lacks a provision preventing the FDA from going forward with its proposed plan to ban certain metered-dose inhalers.

I have introduced legislation, and myself and other colleagues have worked hard to try and lobby the conference. We were not successful. The FDA is proposing to ban metered-dose inhalers containing chlorofluorocarbons sooner than America agreed to in the Montreal Protocol. I am going to reach out to both sides to see if we can pass a standing piece of legislation, because CFC damage is there, it hurts the ozone layer, but, frankly, we need to phase it out and not move abruptly.

The Federal Government allows the use of CFCs for bear repellent and wasp and hornet sprays, yet the FDA wants to take away medicines for metered-dose inhalers because they have CFCs. Are killing bugs and chasing away bears really more important than the health of our children? I do not think so. Next session, Mr. Speaker, let us keep the FDA from banning these inhalers until safe and effective alternatives are developed.

Mr. DINGELL. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from Rhode Island [Mr. KENNEDY].

(Mr. KENNEDY of Rhode Island asked and was given permission to revise and extend his remarks.)

Mr. KENNEDY of Rhode Island. Mr. Speaker, I thank my colleagues who have been speaking out on this issue, most notably the gentleman from Florida, Mr. CLIFF STEARNS, who just spoke. Asthma kills roughly 5,000 people every year. There are over 30 million Americans who depend on those metered-dose inhalers, such as the one I have in my pocket, in order to relieve themselves of the terror of being gripped with asthma.

What the FDA has proposed is they have proposed phasing out these metered-dose inhalers because of their CFC content. CFC content in metered-dose inhalers contributes less than 1 percent of the chlorofluorocarbons in the atmosphere, yet the FDA would like us to believe that by banning these inhalers, we will get about complying with the Montreal Protocol and achieving a reduction in chlorofluorocarbons.

As my colleague, the gentleman from Florida, Mr. CLIFF STEARNS, said, this is all while the EPA has yet to ban refrigeration and air conditioning, which contributes 58,000 tons of CFC's, things such as solvent applications, red pepper bear repellent, lubricant coatings, and foam blown with CFC's used in coaxial cables.

The point I am going to make is we are going after less than 1 percent of the CFC's in the atmosphere by banning these metered-dose inhalers when we have not taken into full account the public health impact on asthmatics all across the country who depend on

these metered-dose inhalers in order to relieve them from their asthma.

I can tell the Members, I have four different inhalers. I think there is only one of them that has a non-CFC component. We should not be rushing to ban these inhalers without fully testing and evaluating the impact of those non-CFC inhalers, so we do not adversely impact the public health of our people.

I want to thank the gentleman from Michigan [Mr. DINGELL] and the gentleman from Virginia, Chairman BLILEY, for agreeing to a bill that will address this issue in the upcoming year.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Kentucky [Mr. WHITFIELD].

(Mr. WHITFIELD asked and was given permission to revise and extend his remarks.)

Mr. WHITFIELD. Mr. Speaker, I thank the gentleman for yielding time to me. I want to give special thanks to the gentleman from Virginia [Mr. BLILEY] and the gentleman from Michigan [Mr. DINGELL] for the leadership they have provided. I rise in strong support of this conference report of FDA reform legislation as it relates to medical devices, prescription drugs, and food.

□ 2030

The food provisions of the final version of this bill reflect closely the hard work of the House in addressing the need for fine-tuning the Nutrition Labeling and Education Act of 1990. Clearly, much more needs to be done before we can assert that our Nation's food laws have been completely reformed. However, this is a responsible down payment of food reform that we can expect to benefit public health.

I want to commend those Members and staff on both sides of the aisle who worked so diligently as we were successful in passing this legislation overwhelmingly. I would urge all Members of the House to support this conference report.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from Pennsylvania [Mr. FOX].

Mr. FOX of Pennsylvania. Mr. Speaker, the gentleman from Virginia [Mr. BLILEY], the chairman, and the gentleman from Michigan [Mr. DINGELL], the ranking member, should be very proud of this legislation.

FDA reform is certainly one of the most important pieces of legislation to pass in this session. I know from testimony in my own home county, Montgomery, Pennsylvania, we had hearings regarding the fact that many people waiting for a cure, a vaccine, whether they have ALS, or cancer, or AIDS or epilepsy, up until now, it took \$5 million and 15 years for many of our drug companies to get approval from FDA.

This legislation will hasten the available market for miracle cures going from lab to the patient without bureaucratic delay. It will speed up that



approval time. Independent agencies will be able to do the testing. This will be a lifesaving procedure because of this legislation's adoption.

I also want to thank the gentleman from Florida [Mr. BILIRAKIS], the gentleman from North Carolina [Mr. BURR], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Texas [Mr. BARTON] for all of their leadership on this issue, because Americans, in a bipartisan fashion, want to have the drugs that are available for them to live longer and to live better. And the same applies, of course, to medical devices and biologics. I appreciate the support of every Member of this entire House to support this FDA reform.

Mr. BLILEY. Mr. Speaker, I yield 1 minute to the gentleman from California [Mr. BILBRAY], a member of the committee.

Mr. BILBRAY. Mr. Speaker, I have the privilege of representing the 49th District of the State of California, San Diego, which has one of the largest concentrations of pharmaceutical companies in the world, but also has more biotech industries in the area than anywhere else in the world, including a combination of Britain and Japan combined.

Mr. Speaker, I like this bill, and I think my constituents will appreciate this bill, not because of those industries, but because of what it does for consumers.

The fact is, Mr. Speaker, there are two ways of hurting a patient. One is to give them inappropriate treatment. But the other, and sadly all too common way of hurting a patient, is not to provide appropriate treatment and to deny that appropriate treatment to people who are ill.

One of the problems we have had in the past is that there have been medication and treatment that have been denied the American consumer that have been available all over the world. This bill is a progressive, well balanced bill that will finally now improve the situation to allow the American consumer to have what they need desperately: safe, effective drugs, as soon as possible. I appreciate the support for the bill.

Mr. DINGELL. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I think we are witnessing an extraordinary event in this Congress and, indeed, almost in any Congress. In the closing days of the session, with the usual tensions and mischief that exist, we are finding great enthusiasm on a very fine piece of legislation which started out rather under a dark star and which, through some remarkable cooperation, has come to the point where we have not only agreement but firm agreement on a good bill, something which is going to help manufacturers, help the economy, to help the consumers and patients. It is going to help the medical profession, it is going to make Americans safer, and it is going to see to it that good

drugs, safe and efficacious, come more quickly to the marketplace.

It is also going to see to it that the other responsibilities of the Food and Drug Administration are conducted in a more efficient and speedy fashion. It shows what real bipartisanship can do when Members of Congress on both sides of the aisle get together and when there can be the kind of cooperation and goodwill there was in the conduct of this particular negotiation.

The result is a fine piece of legislation, one which will benefit the country, one which will benefit the industry, one which will make for better government, and one which will do something else, and that is to protect the consumer and see to it that we get to the American people the best drugs in the fastest and safest and the most assured fashion. I urge my colleagues to support the bill.

I want to commend my colleague, the gentleman from Virginia [Mr. BLILEY], for his fine leadership in this matter. And I want to express my personal thanks and that of the Members on this side of the aisle to Kay Holcombe for the superb job that she has done in preparing this piece of legislation for consideration today. I also am grateful to Secretary Shalala, Dr. Friedman, and the excellent FDA staff for their assistance.

Mr. Speaker, I yield back the balance of my time.

Mr. BLILEY. Mr. Speaker, I thank the gentleman from Michigan [Mr. DINGELL] for his kind words. Without his help, we would not be here.

Mr. Speaker, I yield the balance of our time to the gentleman from Iowa [Mr. GANSKE].

Mr. GANSKE. Mr. Speaker, my congratulations to all who have been involved with this bill.

As a physician, I am very proud to be in favor of this bill. This bill will help bring new and better drugs and medical devices to the market. It will also help older drugs be better used. There are many off-label uses of older drugs that are beneficial to our constituents, like aspirin to prevent heart attacks; 80 to 90 percent of cancer treatment is off-label. In fact, for some diseases, off-label treatment is a standard of care.

Section 7 of H.R. 1411 improves to help public health by increasing the amount of accurate, balanced, scientific information that is available to physicians and other health care professionals. This has been an important compromise between the administration, the FDA, and a bipartisan Congress.

Secretary Shalala said the language that we have agreed to will give the FDA the opportunity to review new information in advance of its dissemination to ensure that it is accurate and balanced. This provision is supported by the AMA, the American Cancer Society, the National Multiple Sclerosis Society, and many other groups who know that greater dissemination of scientific information means better care for patients.

Please vote for this bill.

Mr. WHITFIELD. Mr. Speaker, thanks are owed to several Members for their leading role in the development of the food provisions of this bill. Special thanks must be given to Chairman BLILEY, ranking minority member DINGELL, as well as Messrs. TOWNS, HALL, GANKSE, and of course, the author of the food reform legislation in the last Congress, Mr. KLUG. Praise is also due to the exceptional work of committee counsel, Eric Berger, as well as James Derderian and to staff of members of the committee including Tim Taylor of my staff, Brenda Pillors, Grace Warren, and Jon Traub. Special note should be made of the work of Kay Holcombe, who has served the Commerce Committee and Public Health as a whole with extraordinary professionalism of many years.

The food provision of the final version of this bill reflects closely the hard work of the House in addressing the need for fine tuning of The Nutrition Labeling and Education Act of 1990 [NLEA]. Clearly, much more needs to be done before we can assert that our Nation's food law has been reformed. However, this is a responsible down payment of food reform that we may reasonably expect to benefit public health.

A compelling problem that is addressed by this legislation is the Food and Drug Administration blocking truthful, nonmisleading information from American consumers. As a matter of public health, this has prevented, either by prohibition or excessive delay, consumers from receiving important information about the nutritional content or health benefits of various foods. This problem also takes the form of an abridgement of the first amendment rights of persons who seek to make truthful, nonmisleading statements about a food. FDA has an absolute duty to act within statutory time frames for action on petitions for claims. The failure to do so would constitute a violation of first amendment rights of petitioners. Particularly given the vulnerability of petitioners to retaliation from the FDA, the courts are urged to be expansive in issues of standing in suits regarding failure by the agency to take timely action.

Specifically, the conferees have brought forth a bill that addresses these issues by providing a maximum review time for final action on petitions for claims, including a requirement that the Secretary report on any instances where final action is not taken within the 540 day review period so that the committees of jurisdiction may be promptly informed of a breakdown in the regulatory scheme. Also, special streamlined review mechanisms are provided for health or content claims that are based on the conclusions of authoritative scientific bodies, such as the National Academy of Sciences. The Secretary is granted authority to make proposed rules effective immediately as an exceptional tool to assure that the FDA's duty to pre-approve claims can be met without delay that undermines the regulatory scheme or threatens the first amendment right of petitioners. Unnecessary requirements regarding referral statements that accompany certain nutrient content claims have been eliminated under the bill. And, in a matter where both food safety and first amendment rights have been jeopardized by heavy handed regulatory requirements, an important provision of the bill addresses the labeling of foods treated by irradiation.

To implement the irradiation amendment, FDA is to expeditiously conduct a rulemaking to revise its current irradiation disclosure requirement. The current requirements of the rule, a "Treated with Radiation" or "Treated by Radiation" statement, accompanied by the international radura symbol, make clear that the process has been used. However, it is equally clear that this requirement has had the perverse effect of discouraging many consumers from purchasing food that has been made safer by this process. The conferees are concerned that the current disclosure requirement may be perceived as a warning and that it may raise common but inappropriate anxieties about radiation technologies. FDA should use the new rulemaking to assure that disclosures are only required as necessary to inform consumers of a material fact regarding the food. FDA's 1986 preamble to its final rule regarding irradiation disclosure well explained the general rule regarding disclosure of material facts and how that rule relates to food that has been irradiated:

In this case, the standard for misbranding under sections 403(a) and 201(n) of the act is whether the changes brought about by the safe use of irradiation are material facts in light of the representations made, including the failure to reveal material facts, about such foods. Irradiation may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed.

The Agency recognizes, however, that the irradiation of one ingredient in a multiple ingredient food is a different situation, because such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities. Therefore, FDA advises that the labeling requirement applies only to food that has been irradiated when that food has been sold as such (first generation food), not to food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated.

Thus, FDA determined that disclosure is required to convey to consumers the material fact that the food is not fresh or unprocessed. Given the fresh appearance of food treated by irradiation, FDA determined that the omission of such a disclosure would cause a false or misleading presentation of the food. FDA has authority in this regard only to prevent false or misleading presentation of the food. FDA would exceed its authority if it were to prohibit a truthful, nonmisleading presentation of the food. In any situations where FDA determines that an irradiation disclosure remains necessary, it is obliged to achieve that objective in a minimally burdensome manner. Disclosure statements may only be required where presentation of the food would be false or misleading absent a disclosure statement. Statements different from the current disclosure requirement would suffice if they inform consumers of the material fact that is basis for the disclosure requirement. FDA is obliged to permit disclosure of the material fact through any statements that are not false or misleading. Moreover, the conferees expect FDA to take pains to assure that where disclosure is appropriately required, such required statements not give rise to consumer confusion that could be the use of this pathogen reducing technology. It would be unacceptable for FDA to require a disclosure requirement that may

cause consumer confusion with the excuse that the confusion may be corrected by a proper consumer education program. On its face, such an approach creates burdens that inhibit the use of this technology and, as a consequence, food safety.

The conferees strongly support the consumer right to know. The act contemplates that right being addressed through a vast array of truthful, nonmisleading voluntary label statements, as well as required disclosure of material facts that are not obvious in the presentation of a food. With respect to food that has been irradiated, this legislation does not limit FDA's existing authority to require disclosure nor does it forbid use of the international radura symbol as one of the means of making such a disclosure. The conferees expect FDA to continue to require necessary disclosures to prevent consumers from being misled about any material fact about a food.

Also in the area of labeling, I am disappointed to note that the Senate conferees would not accept the elimination of antiquated and bizarre provisions of the Food, Drug and Cosmetic Act that apply only to margarine. It is a sad measure of our food regulatory system when industries seek competitive advantage over one another through the imposition and maintenance of absurdly burdensome requirements such as these.

I am pleased to report that the conferees have agreed to direction for FDA to take final action within 60 days on the petition to permit the irradiation of beef. This petition has been pending in FDA for over 3 years, despite the requirement that FDA act on such petitions within 6 months. Also, the bill includes reforms in the review of food labeling packaging materials that should assist FDA in expediting appropriate approval of both these materials and, through greater efficiency of operation, all food additive petitions.

I urge my colleagues to vote for the conference report so that we may make this down payment on food law reform.

Mr. TOWNS. Mr. Chairman, I join my colleagues in applauding the scheduling of the conference report on S. 830, legislation to reform the Food and Drug Administration, prior to our adjournment of the 1st session of the 105th Congress. This bill is the culmination of 2 years of hard bipartisan work by the Commerce Committee to modernize procedures that the Food and Drug Administration uses to approve drugs, devices and food products. Once again, Mr. Chairman, the Commerce Committee under the able leadership of our chairman, Mr. BILEY, and our ranking member, Mr. DINGELL, have demonstrated that we have the ability to develop comprehensive legislative responses to critical public policy questions. I also want to especially acknowledge the efforts of our subcommittee chairman, Mr. BLURAKS and our ranking subcommittee member, Mr. BROWN, for the willingness to guide the deliberations on this bill in a bipartisan fashion.

Without the modernizing steps that have been incorporated in this legislation today, the FDA would continue to be seen as a barrier to new innovative therapies and products. The bill before us today represents a careful balance between a new, streamlined process and consumer protections against harmful products. These innovations in the way the FDA will do business from now on makes the approval of drugs and devices a more predictable process.

Finally, Mr. Chairman, I am most pleased about the provisions in this bill which relate to food products. I had the wonderful experience of working closely on these issues in a bipartisan fashion with the gentleman from Kentucky [Mr. WHITFIELD], the gentleman from Wisconsin [Mr. KLUG], the gentleman from Pennsylvania [Mr. GREENWOOD], and the gentleman from Texas [Mr. HALL]. While some argued that food reforms were too controversial to include in this bill, my colleagues and I never stopped believing that we could craft reasonable and meaningful food reforms that would be acceptable to the industry, FDA, and consumers alike. With the able assistance of our committee counsels on both sides of the aisle, Eric Berger and Kay Holcombe, the measure incorporated in S. 830 accomplish this goal. The food issues in this bill build on the success of the Nutrition Labeling and Education Act and they represent a modest downpayment on more significant food law reforms, including the question of national uniformity.

Mr. Chairman, I join my colleagues from the Commerce Committee in urging the immediate passage of this legislation.

Mr. RAMSTAD. Mr. Speaker, I rise in strong support of the Conference Report on comprehensive legislation to reform the Food and Drug Administration [FDA]. And I thank Chairman BILEY and the others who worked so hard to bring this important Conference Report to the floor for passage before Congress adjourns for the year.

Reforming the FDA's approval process has been a major goal of mine since I first came to Congress in 1991. In fact, in an effort to educate House members about the need for reform for medical devices, Representative Tim Valentine and I founded the bipartisan House Medical Technology Caucus, which I now chair with Representative ANNA ESHOO.

As we all know, it now takes 15 years and \$350 million to get the average new drug from the laboratory to the patient. The average time for the FDA to approve a medical device has increased from 415 days in 1990 to 773 in 1995—even though the FDA is currently required by law to take no longer than 180 days to approve new devices.

This is precisely why I became an original cosponsor of the medical device section of this reform package. The medical device provisions will save lives, improve health and create jobs in the United States by getting medical devices to market faster.

I also strongly support the sections in the bill to reauthorize the Prescription Drug User Fee Act [PDUFA] and reform the approval process for pharmaceuticals and animal drugs.

Mr. Speaker, these reforms passed today will force the FDA to get its act together so life-saving devices and drugs will get to people who need them as expeditiously and safely as possible.

The health care consumers, medical device and pharmaceutical companies of America deserve nothing less!

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Virginia [Mr. BILEY] that the House suspend the rules and agree to the conference report on S. 830.

The question was taken; and (two-thirds having voted in favor thereof)

the rules were suspended and the conference report was agreed to.

A motion to reconsider was laid on the table.

# SENSE OF HOUSE IN SUPPORT OF FREE AND FAIR REFERENDUM ON SELF-DETERMINATION FOR PEOPLE OF WESTERN SAHARA

Mr. ROYCE. Mr. Speaker, I move to suspend the rules and agree to the resolution (H. Res. 245) expressing the sense of the House of Representatives in support of a free and fair referendum on self-determination for the people of Western Sahara, as amended.

The Clerk read as follows:

## H. RES. 245

Whereas United Nations Secretary General Kofi Annan appointed former United States Secretary of State James Baker III as his Personal Envoy for Western Sahara to end the prevailing referendum stalemate;

Whereas talks between the Kingdom of Morocco and the Front for the Liberation of Saguia el Hamra and Rio de Oro (also known as the Polisario Front) mediated by Mr. Baker have achieved agreement on ways to end the referendum stalemate;

Whereas the end of the stalemate over the Western Sahara referendum would allow for the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front; and

Whereas the United States supports the holding of a free, fair, and transparent referendum on self-determination for the people of Western Sahara: Now, therefore, be it

*Resolved*, That the House of Representatives—

(1) expresses its full support to former United States Secretary of State James Baker III in his mission as Personal Envoy of the United Nations Secretary General for the Western Sahara;

(2) expresses its support for a referendum on self-determination for the people of Western Sahara that should meet the following criteria:

(A) free, fair, and transparent and held in the presence of international and domestic observers and international media without administrative or military pressure or interference;

(B) only genuine Sahrawis, as identified in the method agreed to by both sides, will take part in the referendum voting; and

(C) the result, once certified by the United Nations, is accepted by both sides;

(3) encourages the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front at the earliest possible date; and

(4) requests the administration to fully support former United States Secretary of State James Baker III in his mission of organizing a free, fair, and transparent referendum on self-determination for the people of Western Sahara without military or administrative constraints.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from California [Mr. ROYCE] and the gentleman from California [Mr. MENENDEZ] each will control 20 minutes.

The Chair recognizes the gentleman from California [Mr. ROYCE].

## GENERAL LEAVE

Mr. ROYCE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to

revise and extend their remarks on this measure.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from California?

There was no objection.

Mr. ROYCE. Mr. Speaker, I yield myself such time as I may consume.

This resolution expresses the support of the House of Representatives for the so-far successful negotiations between the Kingdom of Morocco and the Polisario Front, who have made the tough decision to peacefully work out their differences on the conduct of a referendum on self-determination for Western Sahara. The negotiations have been guided by former Secretary of State James Baker, now serving as the Special Envoy of the U.N. Secretary General for Western Sahara.

Secretary Baker's diplomacy have broken a 6-year stalemate on referendum negotiations. While no date has been set for balloting, we appear to be closer to fair and free referendum for Western Sahara than at any time in the last two decades. This conflict, which has often seemed intractable, has not received the attention it deserves. This is now changing with Secretary Baker's engagement, as well as with the attention that Congress is now paying to this issue.

This resolution not only praises the efforts of Secretary Baker but it puts the House on record as supporting a free, fair, and transparent referendum. At this sensitive point in the process, such a nonpartisan expression of support is valuable. Mr. Baker said in a Washington news conference last week that this resolution provides a much needed boost to a referendum process he referred to as the "last opportunity for peace" in Western Sahara.

Years of fighting between Morocco, the Polisario Front, and Mauritania have claimed thousands of lives and created hundreds of thousands of refugees. The equitable ending of this conflict is important to the United States. Morocco is a longstanding American ally, and continued turmoil in the region is contrary to United States interests.

The breakthrough achieved by Secretary Baker is important. That is why we need to take proper notice of it. It is time to show all parties that the United States is watching and cares. I urge my colleagues to support this balanced resolution as a sign of congressional support for the significant advance that has taken place toward resolving this longstanding conflict.

Mr. Speaker, I reserve the balance of my time.

Mr. MENENDEZ. Mr. Speaker, I yield myself such time as I may consume.

(Mr. MENENDEZ asked and was given permission to revise and extend his remarks.)

Mr. MENENDEZ. Mr. Speaker, I rise in strong support of House Resolution 245, expressing the sense of the House in support of a free and fair referendum on self-determination for the people of Western Sahara.

Mr. Speaker, I think we owe a great deal of gratitude to former Secretary of State James Baker for his service as Special Envoy. Clearly, it was his intervention which brought an end to the referendum impasse and which has allowed for an opportunity for peace in the region.

For too long, the situation in the Western Sahara has been left unresolved, and for too long it has caused tension in the region and within the African continent. It is crucial at this juncture that the U.S. Government and the Congress put their weight behind the plan negotiated by former Secretary Baker. There is only a small window of opportunity to implement the agreement, which itself remains quite fragile. If we bypass this opportunity by our inattention or if we allow either side to renege on the commitments made in Houston, we will be responsible for foregoing an opportunity for long-term peace in the region. That is not a cost we can afford, and it is a small price to pay for peace and democracy.

The Houston plan has at long last found a resolution which is acceptable to both the Moroccan Government and the Polisario Front. The referendum, which will be held next December, will grant the Sahrawi people their long-awaited right to self-determination, the same right enjoyed by free people throughout the world.

Sahrawi President Abdelaziz has given his word that he will stand by and respect the people's decision regardless of the outcome as long as the referendum is free and fair and allows only Sahrawis to vote. The Sahrawi people have been left in limbo due to political considerations rather than any really legal dispute.

In 1975, the International Court of Justice declared that there is no establishment of any legal ties of territorial sovereignty between the territory of Western Sahara and the Kingdom of Morocco. Now the Sahrawi people will have the opportunity to decide for themselves their political future, be it independence or incorporation into Morocco. It is their choice.

I want to thank the gentleman from California [Mr. ROYCE] for his leadership in bringing the resolution before the House and for sponsoring it. I am proud to be an original cosponsor. And I also want to again congratulate former Secretary Baker for his tremendous efforts. He has been and we expect will continue to be crucial to the success of this ultimate endeavor.

Mr. Speaker, I reserve the balance of my time.

□ 2045

Mr. ROYCE. Mr. Speaker, I yield 2 minutes to the gentleman from New York [Mr. GILMAN], the distinguished chairman of the Committee on International Relations.

(Mr. GILMAN asked and was given permission to revise and extend his remarks.)

state veterans' cemeteries funded under the grant program. This provision would authorize the Secretary to grant up to 100 percent of the cost of improvements to the land to be purchased and up to 100 percent of the initial

equipment costs. For existing cemeteries, the Secretary would be authorized to grant up to 100 percent of the cost of the improvements made to any additional land purchased for expansion or 100 percent of the

cost of improvements to existing cemetery land.

#### Compromise agreement

The compromise bill contains no provision relating this subject.

## NOTICE

*Incomplete record of House proceedings. Except for concluding business which follows, today's House proceedings will be continued in the next issue of the Record.*

### CONFERENCE REPORT ON S. 830, FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

Mr. BLILEY submitted the following conference report and statement on the Senate bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes:

#### CONFERENCE REPORT (H. REPT. 105-399)

The Committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

#### SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the "Food and Drug Administration Modernization Act of 1997".

(b) **REFERENCES.**—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; references; table of contents.  
Sec. 2. Definitions.

#### TITLE I—IMPROVING REGULATION OF DRUGS

##### Subtitle A—Fees Relating to Drugs

Sec. 101. Findings.  
Sec. 102. Definitions.  
Sec. 103. Authority to assess and use drug fees.  
Sec. 104. Annual reports.  
Sec. 105. Savings.  
Sec. 106. Effective date.  
Sec. 107. Termination of effectiveness.

##### Subtitle B—Other Improvements

Sec. 111. Pediatric studies of drugs.  
Sec. 112. Expediting study and approval of fast track drugs.  
Sec. 113. Information program on clinical trials for serious or life-threatening diseases.  
Sec. 114. Health care economic information.  
Sec. 115. Clinical investigations.  
Sec. 116. Manufacturing changes for drugs.  
Sec. 117. Streamlining clinical research on drugs.

Sec. 118. Data requirements for drugs and biologics.

Sec. 119. Content and review of applications.

Sec. 120. Scientific advisory panels.

Sec. 121. Positron emission tomography.

Sec. 122. Requirements for radiopharmaceuticals.

Sec. 123. Modernization of regulation.

Sec. 124. Pilot and small scale manufacture.

Sec. 125. Insulin and antibiotics.

Sec. 126. Elimination of certain labeling requirements.

Sec. 127. Application of Federal law to practice of pharmacy compounding.

Sec. 128. Reauthorization of clinical pharmacology program.

Sec. 129. Regulations for sunscreen products.

Sec. 130. Reports of postmarketing approval studies.

Sec. 131. Notification of discontinuance of a life saving product.

#### TITLE II—IMPROVING REGULATION OF DEVICES

Sec. 201. Investigational device exemptions.

Sec. 202. Special review for certain devices.

Sec. 203. Expanding humanitarian use of devices.

Sec. 204. Device standards.

Sec. 205. Scope of review; collaborative determinations of device data requirements.

Sec. 206. Premarket notification.

Sec. 207. Evaluation of automatic class III designation.

Sec. 208. Classification panels.

Sec. 209. Certainty of review timeframes; collaborative review process.

Sec. 210. Accreditation of persons for review of premarket notification reports.

Sec. 211. Device tracking.

Sec. 212. Postmarket surveillance.

Sec. 213. Reports.

Sec. 214. Practice of medicine.

Sec. 215. Noninvasive blood glucose meter.

Sec. 216. Use of data relating to premarket approval; product development protocol.

Sec. 217. Clarification of the number of required clinical investigations for approval.

#### TITLE III—IMPROVING REGULATION OF FOOD

Sec. 301. Flexibility for regulations regarding claims.

Sec. 302. Petitions for claims.

Sec. 303. Health claims for food products.

Sec. 304. Nutrient content claims.

Sec. 305. Referral statements.

Sec. 306. Disclosure of irradiation.

Sec. 307. Irradiation petition.

Sec. 308. Glass and ceramic ware.

Sec. 309. Food contact substances.

#### TITLE IV—GENERAL PROVISIONS

Sec. 401. Dissemination of information on new uses.

Sec. 402. Expanded access to investigational therapies and diagnostics.

Sec. 403. Approval of supplemental applications for approved products.

Sec. 404. Dispute resolution.

Sec. 405. Informal agency statements.

Sec. 406. Food and Drug Administration mission and annual report.

Sec. 407. Information system.

Sec. 408. Education and training.

Sec. 409. Centers for education and research on therapeutics.

Sec. 410. Mutual recognition agreements and global harmonization.

Sec. 411. Environmental impact review.

Sec. 412. National uniformity for nonprescription drugs and cosmetics.

Sec. 413. Food and Drug Administration study of mercury compounds in drugs and food.

Sec. 414. Interagency collaboration.

Sec. 415. Contracts for expert review.

Sec. 416. Product classification.

Sec. 417. Registration of foreign establishments.

Sec. 418. Clarification of seizure authority.

Sec. 419. Interstate commerce.

Sec. 420. Safety report disclaimers.

Sec. 421. Labeling and advertising regarding compliance with statutory requirements.

Sec. 422. Rule of construction.

#### TITLE V—EFFECTIVE DATE

Sec. 501. Effective date.

#### SEC. 2. DEFINITIONS.

In this Act, the terms "drug", "device", "food", and "dietary supplement" have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

#### TITLE I—IMPROVING REGULATION OF DRUGS

##### Subtitle A—Fees Relating to Drugs

#### SEC. 101. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of

the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.

#### SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—  
(A) by striking "Service Act, and" and inserting "Service Act.", and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.";

(2) in the second sentence of paragraph (3)—  
(A) by striking "Service Act, and" and inserting "Service Act.", and

(B) by striking "September 1, 1992." and inserting the following: "September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.";

(3) in paragraph (4), by striking "without" and inserting "without substantial";

(4) by amending the first sentence of paragraph (5) to read as follows:

"(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form.";

(5) in paragraph (7)(A)—

(A) by striking "employees under contract" and all that follows through "Administration," the second time it occurs and inserting "contractors of the Food and Drug Administration,"; and

(B) by striking "and committees," and inserting "and committees and to contracts with such contractors.";

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking "August of" and inserting "April of"; and

(ii) by striking "August 1992" and inserting "April 1997"; and

(B) in subparagraph (B)—

(i) by striking "section 254(d)" and inserting "section 254(c)";

(ii) by striking "1992" and inserting "1997"; and

(iii) by striking "102d Congress, 2d Session" and inserting "105th Congress, 1st Session"; and

(7) by adding at the end the following:

"(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has power to control, both of the business entities.".

#### SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking "Beginning in fiscal year 1993" and inserting "Beginning in fiscal year 1998";

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

"(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.";

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking "NOT ACCEPTED" and inserting "REFUSED";

(ii) by striking "50 percent" and inserting "75 percent";

(iii) by striking "subparagraph (B)(i)" and inserting "subparagraph (B)"; and

(iv) by striking "not accepted" and inserting "refused"; and

(C) by adding at the end the following:

"(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement."

"(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A)."

"(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.";

(3) by striking paragraph (2) and inserting the following:

"(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each person that—

"(i) is named as the applicant in a human drug application; and

"(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

"(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

"(i) that did not manufacture the product in the previous fiscal year; and

"(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began."; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking "is listed" and inserting "has been submitted for listing"; and

(ii) by striking "Such fee shall be payable" and all that follows through "section 510," and inserting the following: "Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable."; and

(B) in subparagraph (B), by striking "505(j)," and inserting the following: "505(j), under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.".

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

"(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

"(1) APPLICATION AND SUPPLEMENT FEES.—

"(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be \$250,704 in fiscal year 1998, \$256,338 in each of fiscal years 1999 and 2000, \$267,606 in fiscal year 2001, and \$258,451 in fiscal year 2002.

"(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be \$125,352 in fiscal year 1998, \$128,169 in each of fiscal years 1999 and 2000, \$133,803 in fiscal year 2001, and \$129,226 in fiscal year 2002.

"(2) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be \$35,600,000 in fiscal year 1998, \$36,400,000 in each of fiscal years 1999 and 2000, \$38,000,000 in fiscal year 2001, and \$36,700,000 in fiscal year 2002.

"(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year."

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking "INCREASES AND";

(2) in paragraph (1)—

(A) by striking "(1) REVENUE" and all that follows through "increased by the Secretary" and inserting the following: "(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary";

(B) in subparagraph (A), by striking "increase" and inserting "change";

(C) in subparagraph (B), by striking "increase" and inserting "change"; and

(D) by adding at the end the following flush sentence:

"The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.";

(3) in paragraph (2), by striking "October 1, 1992," and all that follows through "such



schedule." and inserting the following: "September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b)."; and

(4) in paragraph (3), by striking "paragraph (2)" and inserting "this subsection".

(d) **FEE WAIVER OR REDUCTION.**—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(2) by striking "The Secretary shall grant a" and all that follows through "finds that—" and inserting the following:

"(1) **IN GENERAL.**—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—";

(3) in subparagraph (C) (as so redesignated in paragraph (1)), by striking ", or" and inserting a comma;

(4) in subparagraph (D) (as so redesignated in paragraph (1)), by striking the period and inserting ", or";

(5) by inserting after subparagraph (D) (as so redesignated in paragraph (1)) the following:

"(E) the applicant involved is a small business submitting its first human drug application to the Secretary for review."; and

(6) by striking "In making the finding in paragraph (3)," and all that follows through "standard costs." and inserting the following:

"(2) **USE OF STANDARD COSTS.**—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

"(3) **RULES RELATING TO SMALL BUSINESSES.**—

"(A) **DEFINITION.**—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

"(B) **WAIVER OF APPLICATION FEE.**—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

"(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

"(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.".

(e) **ASSESSMENT OF FEES.**—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking "fiscal year 1993" and inserting "fiscal year 1997"; and

(2) by striking "fiscal year 1992" and inserting "fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)".

(f) **CREDITING AND AVAILABILITY OF FEES.**—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: "Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "Acts" and inserting "Acts, or otherwise made available for obligation,"; and

(B) in subparagraph (B), by striking "over such costs for fiscal year 1992" and inserting "over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997", and

(3) by striking paragraph (3) and inserting the following:

"(3) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated for fees under this section—

"(A) \$106,800,000 for fiscal year 1998;

"(B) \$109,200,000 for fiscal year 1999;

"(C) \$109,200,000 for fiscal year 2000;

"(D) \$114,000,000 for fiscal year 2001; and

"(E) \$110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

"(4) **OFFSET.**—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year."

(g) **REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.**—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

"(i) **WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.**—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due."

(h) **SPECIAL RULE FOR WAIVERS AND REFUNDS.**—Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (as in effect on September 30, 1997). The term "person" in such Acts shall continue to include an affiliate thereof.

**SEC. 104. ANNUAL REPORTS.**

(a) **PERFORMANCE REPORT.**—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) **FISCAL REPORT.**—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal

year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

**SEC. 105. SAVINGS.**

Notwithstanding section 105 of the Prescription Drug User Fee Act of 1992, the Secretary shall retain the authority to assess and collect any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998.

**SEC. 106. EFFECTIVE DATE.**

The amendments made by this subtitle shall take effect October 1, 1997.

**SEC. 107. TERMINATION OF EFFECTIVENESS.**

The amendments made by sections 102 and 103 cease to be effective October 1, 2002, and section 104 ceases to be effective 120 days after such date.

#### Subtitle B—Other Improvements

#### SEC. 111. PEDIATRIC STUDIES OF DRUGS.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

#### "SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

"(a) **MARKET EXCLUSIVITY FOR NEW DRUGS.**—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

"(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

"(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

"(2)(A) if the drug is the subject of—

"(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(viii)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(viii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

"(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

"(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

"(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

"(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

"(2)(A) if the drug is the subject of—  
 "(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vi)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

"(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vi)(III) of section 505, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

"(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vi)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

"(d) CONDUCT OF PEDIATRIC STUDIES.—

"(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (a) or (c), after consultation with—

"(A) the sponsor of an application for an investigational new drug under section 505(i);

"(B) the sponsor of an application for a new drug under section 505(b)(1); or

"(C) the holder of an approved application for a drug under section 505(b)(1), agree with the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for such studies.

"(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and

the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

"(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

"(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(f) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(4)(D), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(f) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under subsection (a) or (c) shall be deemed to have been running during the period of delay.

"(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

"(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups in which a drug is anticipated to be used.

"(h) LIMITATIONS.—A drug to which the six-month period under subsection (a) or (b) has already been applied—

"(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and

"(2) may not receive any additional such period under subsection (c)(1)(B).

"(i) RELATIONSHIP TO REGULATIONS.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

"(j) SUNSET.—A drug may not receive any six-month period under subsection (a) or (c) unless the application for the drug under section

505(b)(1) is submitted on or before January 1, 2002. After January 1, 2002, a drug shall receive a six-month period under subsection (c) if—

"(1) the drug was in commercial distribution as of the date of enactment of the Food and Drug Administration Modernization Act of 1997,

"(2) the drug was included by the Secretary on the list under subsection (b) as of January 1, 2002,

"(3) the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population and that the drug may provide health benefits in that population; and

"(4) all requirements of this section are met.

"(k) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. The study and report shall examine all relevant issues, including—

"(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

"(2) the adequacy of the incentive provided under this section;

"(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and

"(4) any suggestions for modification that the Secretary determines to be appropriate."

#### SEC. 112. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 125, is amended by inserting before section 505 the following:

##### "SEC. 506. FAST TRACK PRODUCTS.

"(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a 'fast track product'.)

"(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

"(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

"(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

"(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

"(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

"(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period



thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(3) **EXPEDITED WITHDRAWAL OF APPROVAL.**—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence.

"(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

"(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(c) **REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.**—

"(1) **IN GENERAL.**—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

"(A) provides a schedule for submission of information necessary to make the application complete; and

"(B) pays any fee that may be required under section 736.

"(2) **EXCEPTION.**—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) **AWARENESS EFFORTS.**—The Secretary shall—

"(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

"(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs."

(b) **GUIDANCE.**—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track products (as defined in section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 506 of such Act.

#### **SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.**

(a) **IN GENERAL.**—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (f) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i) the following:

"(j)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the 'data bank'). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable coordinated with other data banks containing similar information.

"(B) The Secretary shall establish the data bank after consultation with the Commissioner

of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

"(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

"(3) The data bank shall include the following:

"(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(l) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

"(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

"(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

"(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

"(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

"(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection."

(b) **COLLABORATION AND REPORT.**—

(1) **IN GENERAL.**—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act.

(2) **REPORT.**—Not later than two years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act.

(B) on the adverse impact, if any, on device innovation and research in the United States if

information relating to such device investigations is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

#### **SEC. 114. HEALTH CARE ECONOMIC INFORMATION.**

(a) **IN GENERAL.**—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: "Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."

(b) **STUDY AND REPORT.**—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

#### **SEC. 115. CLINICAL INVESTIGATIONS.**

(a) **CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.**—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: "If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence."

(b) **WOMEN AND MINORITIES.**—Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding at the end the following: "The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A)."

#### **SEC. 116. MANUFACTURING CHANGES FOR DRUGS.**

(a) **IN GENERAL.**—Chapter V, as amended by section 112, is amended by inserting after section 506 the following section:

##### **"SEC. 506A. MANUFACTURING CHANGES.**

"(a) **IN GENERAL.**—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

"(1) the holder of the approved application or license (referred to in this section as a 'holder') has validated the effects of the change in accordance with subsection (b), and

"(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c), or

"(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

"(b) **VALIDATION OF EFFECTS OF CHANGES.**—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

"(c) **MAJOR MANUFACTURING CHANGES.**—

"(1) **REQUIREMENT OF SUPPLEMENTAL APPLICATION.**—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

"(2) **CHANGES QUALIFYING AS MAJOR CHANGES.**—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

"(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

"(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

"(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

"(d) **OTHER MANUFACTURING CHANGES.**—

"(1) **IN GENERAL.**—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

"(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

"(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

"(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

"(2) **CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.**—

"(A) **SUBMISSION OF REPORT.**—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

"(B) **AUTHORITY REGARDING ANNUAL REPORTS.**—In the case of a holder that during a

single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

"(3) **CHANGES REQUIRING SUPPLEMENTAL APPLICATION.**—

"(A) **SUBMISSION OF SUPPLEMENTAL APPLICATION.**—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

"(B) **AUTHORITY FOR DISTRIBUTION.**—In the case of a manufacturing change to which paragraph (1)(B) applies:

"(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

"(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

"(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change."

(b) **TRANSITION RULE.**—The amendment made by subsection (a) takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first.

#### SEC. 117. STREAMLINING CLINICAL RESEARCH ON DRUGS.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting "(1)" after "(i)";

(3) by striking the last two sentences; and

(4) by inserting after paragraph (1) (as designated by paragraph (2) of this section) the following new paragraphs:

"(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

"(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

"(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

"(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

"(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

"(i) the drug involved represents an unreasonable risk to the safety of the persons who are

the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

"(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

"(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

"(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

#### SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

#### SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.

(a) **SECTION 505(b).**—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

"(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

"(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

"(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant

shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

“(i) with the written agreement of the sponsor or applicant; or

“(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

“(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

“(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

“(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

“(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).”

(b) SECTION 505(f).—

(1) AMENDMENT.—Section 505(f) (21 U.S.C. 355(f)) is amended—

(A) by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively; and

(B) by adding after paragraph (2) the following:

“(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

“(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

“(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

“(i) with the written agreement of the sponsor or applicant; or

“(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

“(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the direc-

tor and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

“(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

“(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

“(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).”

(2) CONFORMING AMENDMENTS.—Section 505(f) (21 U.S.C. 355(f)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking “(6)” and inserting “(7)”;

(B) in paragraph (4) (as redesignated in paragraph (1)), by striking “(4)” and inserting “(5)”;

(C) in paragraph (4)(1) (as redesignated in paragraph (1)), by striking “(5)” and inserting “(6)”; and

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking “(5)” each place it occurs and inserting “(6)”.

#### SEC. 130. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

“(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

“(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

“(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

“(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

“(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

“(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

“(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

“(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the

panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

“(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

“(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

“(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

“(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.”

#### SEC. 131. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

“(ii) The term ‘compounded positron emission tomography drug’—

“(1) means a drug that—

“(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

“(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

“(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.”

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a) (21 U.S.C. 351(a)) is amended by striking “; or (3)” and inserting the following “; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding

standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)"

(2) **SUNSET.**—Section 301(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later

(C) **REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.**—

(1) **PROCEDURES AND REQUIREMENTS.**—

(A) **IN GENERAL.**—In order to take account of the special characteristics of positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) **CONSIDERATIONS AND CONSULTATION.**—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use positron emission tomography drugs.

(2) **SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.**—

(A) **IN GENERAL.**—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date on which the Secretary establishes procedures and requirements under paragraph (1), whichever is longer.

(B) **EXCEPTION.**—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(d) **REVOCAION OF CERTAIN INCONSISTENT DOCUMENTS.**—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule:

(1) A notice entitled "Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop", published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10594.

(2) A notice entitled "Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability", published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10593.

(3) A final rule entitled "Current Good Manufacturing Practice for Finished Pharmaceuticals, Positron Emission Tomography", published in the Federal Register on April 22, 1997, 62 Fed. Reg. 19493 (codified at part 211 of title 21, Code of Federal Regulations).

(e) **DEFINITION.**—As used in this section, the term "compounded positron emission tomography drug" has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

#### SEC. 122. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) **REQUIREMENTS.**—

(1) **REGULATIONS.**—

(A) **PROPOSED REGULATIONS.**—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) **FINAL REGULATIONS.**—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) **SPECIAL RULE.**—In the case of a radiopharmaceutical, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomical, or pathological processes) common to, or present in, one or more disease states.

(b) **DEFINITION.**—In this section, the term "radiopharmaceutical" means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

#### SEC. 123. MODERNIZATION OF REGULATION.

(a) **LICENSES.**—

(1) **IN GENERAL.**—Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) is amended to read as follows:

"(a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

"(A) a biologics license is in effect for the biological product; and

"(B) each package of the biological product is plainly marked with—

"(i) the proper name of the biological product contained in the package;

"(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

"(iii) the expiration date of the biological product.

"(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

"(B) The Secretary shall approve a biologics license application—

"(i) on the basis of a demonstration that—

"(I) the biological product that is the subject of the application is safe, pure, and potent; and

"(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent, and

"(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1)."

(2) **ELIMINATION OF EXISTING LICENSE REQUIREMENT.**—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking "(d)(1)" and all that follows through "of this section."

(B) in paragraph (2)—

(i) by striking "(2)(A) Upon" and inserting "(d)(1) Upon" and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking "subparagraph (A)" and inserting "paragraph (1)"; and

(ii) by striking "this subparagraph" each place it appears and inserting "this paragraph."

(b) **LABELING.**—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

"(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark."

(c) **INSPECTION.**—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking "virus, serum," and all that follows and inserting "biological product."

(d) **DEFINITION; APPLICATION.**—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsenamine or derivative of arsenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."

(e) **CONFORMING AMENDMENT.**—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking "section 351(a)" and inserting "section 351(i)"; and

(B) by striking "262(a)" and inserting "262(i)"; and

(2) in subparagraph (B)(iii), by striking "product or establishment license under subsection (a) or (d)" and inserting "biologics license application under subsection (a)".

(f) **SPECIAL RULE.**—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

(g) **APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.**—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

"(f) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act."

(h) **EXAMINATIONS AND PROCEDURES.**—Paragraph (3) of section 353(d) of the Public Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

“(3) **EXAMINATIONS AND PROCEDURES.**—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

“(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

“(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.”

#### SEC. 194. PILOT AND SMALL SCALE MANUFACTURE

(a) **HUMAN DRUGS.**—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

“(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.”

(b) **ANIMAL DRUGS.**—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

“(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.”

#### SEC. 195. INSULIN AND ANTIBIOTICS.

(a) **CERTIFICATION OF DRUGS CONTAINING INSULIN.**—

(1) **AMENDMENT.**—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

##### (2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking “506, 507.”

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking “, 506, 507.”

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after “503(b)” the following: “or composed wholly or partly of insulin.”

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting “or” at the end of subparagraph (B), by striking “; or” at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

##### (b) CERTIFICATION OF ANTIBIOTICS.—

(1) **AMENDMENT.**—Section 507 (21 U.S.C. 357) is repealed.

##### (2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out “or 507”, section 201(dd) (21 U.S.C. 321(dd)) is amended by striking “507”, and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking “, certified as an antibiotic under section 507.”

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking “507(d) or (g).”

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking “or 507.”

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (1).

(E) Section 520(l) (21 U.S.C. 360(l)) is amended by striking paragraph (4) and by striking “or Antibiotic Drugs” in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting “or” at the end of para-

graph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking “, certification of such drug for such disease or condition under section 507.”

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking “the submission of an application for certification of the drug under section 507.”, by inserting “or” at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking “, a certificate was issued for the drug under section 507.”, and

(ii) in paragraph (2) by striking “, a certificate has not been issued for the drug under section 507.” and by striking “, approval of an application for certification under section 507.”

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting “or” at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking “”, issue another certification under section 507.”

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking “, if a certification is issued under section 507 for such a drug.”, “, of the issuance of the certification under section 507.”, “, issue another certification under section 507.”, “, of such certification.”, “, of the certification.”, and “, issuance of other certifications.”

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking “, section 507 (d) or (g).”

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting “or” at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking “or 507.”

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking “or 507.”

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking “507,” each place it occurs.

(c) **EXPORTATION.**—Section 802 (21 U.S.C. 382) is amended by adding at the end the following:

“(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).”

##### (d) TRANSITION.—

(1) **IN GENERAL.**—An application that was approved by the Secretary of Health and Human Services before the date of the enactment of this Act for the marketing of an antibiotic drug under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as in effect on the day before the date of the enactment of this Act, shall, on and after such date of enactment, be considered to be an application that was submitted and filed under section 505(b) of such Act (21 U.S.C. 355(b)) and approved for safety and effectiveness under section 505(c) of such Act (21 U.S.C. 355(c)), except that if such application for marketing was in the form of an abbreviated application, the application shall be considered to have been filed and approved under section 505(j) of such Act (21 U.S.C. 355(j)).

(2) **EXCEPTION.**—The following subsections of section 505 (21 U.S.C. 355) shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of such Act (21 U.S.C. 357) before the date of the enactment of this Act: (A)(i) Subsections (c)(2), (d)(6), (e)(4), (j)(2)(A)(viii), (j)(2)(A)(viii), (j)(2)(B), (j)(4)(B), and (j)(4)(D); and

(ii) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information), and

(B) Subsections (b)(2)(A), (b)(2)(B), (b)(3), and (c)(3) if the investigations relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(3) **PUBLICATION.**—For purposes of this section, the Secretary is authorized to make available to the public the established name of each antibiotic drug that was the subject of any application for marketing received by the Secretary for Health and Human Services under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) before the date of enactment of this Act.

(e) **DEFINITION.**—Section 201 (21 U.S.C. 321), as amended by section 121(a)(1), is further amended by adding at the end the following:

“(H) The term ‘antibiotic drug’ means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.”

#### SEC. 196. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) **PRESCRIPTION DRUGS.**—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

“(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol ‘Rx only’.

“(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).”

(b) **MISBRANDED DRUG.**—Section 502(d) (21 U.S.C. 352(d)) is repealed.

##### (c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking “section 502(d) and”.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking “(i)”; and

(B) by striking “(ii)” and all that follows.

#### SEC. 197. APPLICATION OF FEDERAL LAW TO PRACTICE OF PHARMACY COMPOUNDING.

(a) **AMENDMENT.**—Chapter V is amended by inserting after section 503 (21 U.S.C. 353) the following:

##### “SEC. 503A. PHARMACY COMPOUNDING.

“(a) **IN GENERAL.**—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

“(1) is by—

“(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

“(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs, or



"(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

"(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

"(i) the licensed pharmacist or licensed physician; and

"(ii)(I) such individual patient for whom the prescription order will be provided; or

"(II) the physician or other licensed practitioner who will write such prescription order.

"(b) COMPOUNDED DRUG.—

"(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

"(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

"(i) that—

"(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

"(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

"(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

"(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

"(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

"(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

"(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

"(2) DEFINITION.—For purposes of paragraph (1)(D), the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

"(3) DRUG PRODUCT.—A drug product may be compounded under subsection (a) only if—

"(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

"(B) such drug product is compounded in a State—

"(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

"(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

"(c) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

"(d) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

"(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

"(e) APPLICATION.—This section shall not apply to—

"(1) compounded positron emission tomography drugs as defined in section 201(i); or

"(2) radiopharmaceuticals.

"(f) DEFINITION.—As used in this section, the term 'compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."

"(b) EFFECTIVE DATE.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

#### SEC. 128. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102-222 (105 Stat. 1677) is amended—

"(1) in subsection (a), by striking "a grant" and all that follows through "Such grant" and inserting the following: "grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants"; and

"(2) in subsection (b), by striking "to carry out this section" and inserting "and for fiscal years 1998 through 2002 \$3,000,000 for each fiscal year, to carry out this section".

#### SEC. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and

Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

#### SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

#### "SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

"(a) SUBMISSION.—

"(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

"(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

"(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in subsection (a) shall be considered to be public information to the extent that the information is necessary—

"(1) to identify the sponsor; and

"(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

"(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

"(1) that sponsors have entered into agreements to conduct; and

"(2) for which reports have been submitted under subsection (a)(1)."

"(b) REPORT TO CONGRESSIONAL COMMITTEES.—Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report containing—

"(1) a summary of the reports submitted under section 506B of the Federal Food, Drug, and Cosmetic Act;

"(2) an evaluation of—

"(A) the performance of the sponsors referred to in such section in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act; and

"(B) the timeliness of the Secretary's review of the postmarketing studies; and

"(3) any legislative recommendations respecting the postmarketing studies.

#### SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—Chapter V, as amended by section 130, is further amended by inserting after section 506B the following:

#### "SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

"(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

"(1) that is—

"(A) life-supporting;

"(B) life-sustaining; or

"(C) intended for use in the prevention of a debilitating disease or condition;

"(2) for which an application has been approved under section 505(b) or 505(j); and

"(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product.

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

"(b) **REDUCTION IN NOTIFICATION PERIOD.**—The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

"(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

"(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

"(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

"(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

"(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

"(6) the manufacturer can continue the distribution of the drug involved for 6 months.

"(c) **DISTRIBUTION.**—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) to appropriate physician and patient organizations."

#### **TITLE II—IMPROVING REGULATION OF DEVICES**

##### **SEC. 301. INVESTIGATIONAL DEVICE EXEMPTIONS.**

(a) **IN GENERAL.**—Section 520(g) (21 U.S.C. 360(g)) is amended by adding at the end the following:

"(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

"(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

"(ii) changes or modifications to clinical protocols that do not affect—

"(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

"(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

"(III) the rights, safety, or welfare of the human subjects involved in the investigation.

"(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

"(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

"(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

"(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30

days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

"(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

"(C) A decision under subparagraph (B)(ii) by the director shall be in writing; and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved."

(b) **ACTION ON APPLICATION.**—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

"(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

"(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

"(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending."

##### **SEC. 302. SPECIAL REVIEW FOR CERTAIN DEVICES.**

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by adding at the end the following:

"(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

"(A) representing breakthrough technologies,

"(B) for which no approved alternatives exist,

"(C) which offer significant advantages over existing approved alternatives, or

"(D) the availability of which is in the best interest of the patients."

##### **SEC. 303. EXPANDING HUMANITARIAN USE OF DEVICES.**

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding after and below subparagraph (C) the following sentences:

"The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application."

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after "(2)(A)" the following: " , unless a physician determines in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient"; and

(B) by adding after and below subparagraph (B) the following

"In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use."

(3) by amending paragraph (5) to read as follows:

"(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met."

(4) by amending paragraph (6) to read as follows:

"(6) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing."

##### **SEC. 304. DEVICE STANDARDS.**

(a) **ALTERNATIVE PROCEDURE.**—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

"Recognition of a Standard

"(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a pre-market submission requirement or other requirement under this Act to which such standard is applicable.

"(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

"(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

"(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

"(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

"(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

"(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

"(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data



and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer."

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(z) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section."

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking "(e)" and inserting "(e)(1)"; and

(2) by inserting at the end the following:

"(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 514(c) unless such device is in all respects in conformity with such standard."

(d) CONFORMING AMENDMENTS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(1) in paragraph (1), in the second sentence, by striking "under this section" and inserting "under subsection (b)";

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking "under this section" and inserting "under subsection (b)";

(3) in paragraph (3), by striking "under this section" and inserting "under subsection (b)"; and

(4) in paragraph (4), in the matter preceding subparagraph (A), by striking "this section" and inserting "this subsection and subsection (b)".

#### SEC. 206. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

(a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

"(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

"(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

"(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

"(iii) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determina-

tion by the Secretary could be contrary to the public health."

(b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

"(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

"(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

"(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the 'Director') may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

"(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

"(II) that such use could cause harm.

"(ii) Such determination shall—

"(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

"(II) specify the limitations on the use of the device not included in the proposed labeling; and

"(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

"(iii) The responsibilities of the Director under this subparagraph may not be delegated.

"(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997."

(c) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

"In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling;" and

(2) by adding after paragraph (5) (as added by section 202(2)) the following:

"(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the

Secretary that the change has been made under the requirements of section 520(f).

"(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

"(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

"(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

"(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

"(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness."

#### SEC. 206. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), in the matter preceding paragraph (1), by adding after "report to the Secretary" the following: "or person who is accredited under section 523(a)"; and

(2) by adding at the end the following subsections:

"(l) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

"(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register.

"(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary

regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted."

(b) SECTION 513(f).—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

"(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health)."

(c) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—

(A) in subclause (I), by striking "clinical data" and inserting "appropriate clinical or scientific data" and by inserting "or a person accredited under section 523" after "Secretary"; and

(B) in subclause (II), by striking "efficacy" and inserting "effectiveness"; and

(2) by adding at the end the following:

"(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l)."

SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)), as amended by section 206(b), is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking "paragraph (2)" and inserting "paragraph (3)"; and

(B) in the last sentence, by striking "paragraph (2)" and inserting "paragraph (2) or (3)";

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

"(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

"(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

"(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

"(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification."

#### SEC. 208. CLASSIFICATION PANELS.

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

"(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

"(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

"(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

"(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

"(iii) the same opportunity as the Secretary to participate in meetings of the panel.

"(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review; and shall encourage free and open participation by all interested persons.

"(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

"(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act."

#### SEC. 209. CERTAINTY OF REVIEW TIMEFRAMES; COLLABORATIVE REVIEW PROCESS.

(a) CERTAINTY OF REVIEW TIMEFRAMES.—Section 510 (21 U.S.C. 360), as amended by section 206(a)(2), is amended by adding at the end the following subsection:

"(n) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report."

(b) COLLABORATIVE REVIEW PROCESS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 202(1), is amended by inserting after paragraph (2) the following:

"(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

"(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

"(iii) The Secretary shall notify the applicant promptly of—

"(I) any additional deficiency identified in the application; or

"(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

"(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

#### SEC. 210. ACCREDITATION OF PERSONS FOR REVIEW OF PREMARKET NOTIFICATION REPORTS.

(a) IN GENERAL.—Subchapter A of chapter V is amended by adding at the end the following:

##### "SEC. 523. ACCREDITED PERSONS.

"(a) IN GENERAL.—

"(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

"(2) REQUIREMENTS REGARDING REVIEW.—

"(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

"(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

"(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

"(3) CERTAIN DEVICES.—

"(A) IN GENERAL.—An accredited person may not be used to perform a review of—

"(i) a class III device;

"(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

"(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

"(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

"(b) ACCREDITATION.—

"(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

"(2) ACCREDITATION.—

"(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

"(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the

requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

"(C) **PERFORMANCE AUDITING.**—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

"(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person, and

"(ii) take such additional measures as the Secretary determines to be appropriate.

"(D) **ANNUAL REPORT.**—The Secretary shall include in the annual report required under section 503(g) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

"(3) **QUALIFICATIONS.**—An accredited person shall, at a minimum, meet the following requirements:

"(A) Such person may not be an employee of the Federal Government.

"(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

"(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

"(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

"(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

"(i) certify that reported information accurately reflects data reviewed;

"(ii) limit work to that for which competence and capacity are available;

"(iii) treat information received, records, reports, and recommendations as proprietary information;

"(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

"(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

"(4) **SELECTION OF ACCREDITED PERSONS.**—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

"(5) **COMPENSATION OF ACCREDITED PERSONS.**—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

"(c) **DURATION.**—The authority provided by this section terminates—

"(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k), or

"(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection, whichever occurs first."

(b) **RECORDKEEPING.**—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

"(f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

"(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary."

(c) **CONFORMING AMENDMENT.**—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

"(y) In the case of a drug, device, or food—

"(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

"(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

"(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act."

(d) **REPORTS ON PROGRAM OF ACCREDITATION.**—

(1) **COMPTROLLER GENERAL.**—

(A) **IMPLEMENTATION OF PROGRAM.**—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the program of accreditation required by the amendment made by subsection (a) has been implemented.

(B) **EVALUATION OF PROGRAM.**—Not later than 6 months prior to the date on which, pursuant to subsection (c) of section 523 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a), the authority provided under subsection (a) of such section will terminate, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(2) **INCLUSION OF CERTAIN DEVICES WITHIN PROGRAM.**—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report providing a determination by the Secretary of whether, in the program of accreditation established pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 523(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act (relating to class II devices for which clinical data are required in reports under section 510(k)) should be removed.

## SEC. 211. DEVICE TRACKING.

Effective 90 days after the date of the enactment of this Act, section 519(e) (21 U.S.C. 360(e)) is amended to read as follows:

### "Device Tracking

"(e)(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

"(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

"(B) which is—

"(i) intended to be implanted in the human body for more than one year, or

"(ii) a life sustaining or life supporting device used outside a device user facility.

"(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking."

## SEC. 212. POSTMARKET SURVEILLANCE.

Effective 90 days after the date of the enactment of this Act, section 522 (21 U.S.C. 360i) is amended to read as follows:

### "POSTMARKET SURVEILLANCE

"SEC. 522. (a) **IN GENERAL.**—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

"(1) implanted in the human body for more than one year, or

"(2) a life sustaining or life supporting device used outside a device user facility.

"(b) **SURVEILLANCE APPROVAL.**—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562."

## SEC. 213. REPORTS.

(a) **REPORTS.**—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "manufacturer, importer, or distributor" and inserting "manufacturer or importer";

(B) in paragraph (4), by striking "manufacturer, importer, or distributor" and inserting "manufacturer or importer";

(C) in paragraph (7), by adding "and" after the semicolon at the end;

(D) in paragraph (8)—

(i) by striking "manufacturer, importer, or distributor" each place such term appears and inserting "manufacturer or importer"; and

(ii) by striking the semicolon at the end and inserting a period;

(E) by striking paragraph (9); and

(F) by inserting at the end the following sentence: "The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to

the same extent and in the same manner as such paragraphs apply to manufacturers and importers."

(2) by striking subsection (d); and  
(3) in subsection (f), by striking "importer, or distributor" each place it appears and inserting "or importer".

(b) **REGISTRATION.**—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3) the following:

"(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repack, process, or relabel a device; or"; and

(3) by adding at the end the following flush sentence:

"In this subsection, the term 'wholesale distributor' means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user."

(c) **DEVICE USER FACILITIES.**—

(1) **IN GENERAL.**—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking "a semi-annual basis" and inserting "an annual basis";

(ii) in the second sentence, by striking "and July 1"; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "or" after the comma at the end;

(ii) in subparagraph (B), by striking "or" at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) **SENTINEL SYSTEM.**—Section 519(b) (21 U.S.C. 360(b)) is amended—

(A) by redesignating paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

"(5) With respect to device user facilities:

"(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

"(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

"(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

"(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the facility is included in the subset referred to in subparagraph (A).

"(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan."

**SEC. 214. PRACTICE OF MEDICINE.**

Chapter IX is amended by adding at the end the following

"**SEC. 906. PRACTICE OF MEDICINE.**

"Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any con-

dition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices."

**SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.**

(a) **FINDINGS.**—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly \$100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children; and

(9) the Food and Drug Administration is responsible for reviewing all applications for new medical devices in the United States.

(b) **SENSE OF CONGRESS.**—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

**SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.**

(a) **USE OF DATA RELATING TO PREMARKET APPROVAL.**—

(1) **IN GENERAL.**—Section 520(h)(4) (21 U.S.C. 360f(h)(4)) is amended to read as follows:

"(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

"(i) approving another device;

"(ii) determining whether a product development protocol has been completed, under section 515 for another device;

"(iii) establishing a performance standard or special control under this Act; or

"(iv) classifying or reclassifying another device under section 513 and subsection (1)(2).

"(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A)."

(2) **CONFORMING AMENDMENTS.**—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(A) in paragraph (8), by adding "or" at the end;

(B) in paragraph (9), by striking "or" and inserting a comma; and

(C) by striking paragraph (10).

(b) **PRODUCT DEVELOPMENT PROTOCOL.**—Section 515(f)(2) (21 U.S.C. 360e(f)(2)) is amended by striking "he shall" and all that follows and inserting the following: "the Secretary—

"(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

"(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel."

**SEC. 217. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.**

Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking "clinical investigations" and inserting "1 or more clinical investigations".

### TITLE III—IMPROVING REGULATION OF FOOD

**SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.**

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

"(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

"(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

"(i) enable consumers to develop and maintain healthy dietary practices;

"(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

"(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

"(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph. Such proposed regulations shall be deemed final agency action for purposes of judicial review."

**SEC. 302. PETITIONS FOR CLAIMS.**

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: "If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner."

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: "or the petition is deemed to be denied"; and

(3) by adding at the end the following: "If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days."

**SEC. 303. HEALTH CLAIMS FOR FOOD PRODUCTS.**

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

"(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be

authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(D) A claim submitted under the requirements of clause (C) may be made until—

"(i) such time as the Secretary issues a regulation under the standard in clause (B)(i);

"(II) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met."

#### SEC. 304. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

"(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

"(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

"(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has

not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

"(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

"(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

"(H) A claim submitted under the requirements of clause (G) may be made until—

"(i) such time as the Secretary issues a regulation—

"(I) prohibiting or modifying the claim and the regulation has become effective, or

"(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

"(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met."

#### SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet."

#### SEC. 306. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

##### "DISCLOSURE

"SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

"(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food has been intentionally subjected to radiation."

#### SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any petition pending with the Food and Drug Administration that would per-

mit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 60 days following the date of the enactment of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

#### SEC. 308. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based enamel in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and

(2) which is not, by design, representation, or custom of usage intended for use by children,

is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware. Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.

#### SEC. 309. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking "subsection (i)" and inserting "subsection (j)"; and

(B) by striking at the end "or";

(2) by striking the period at the end of paragraph (2) and inserting "; or";

(3) by inserting after paragraph (2) the following:

"(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

"(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

"(B) a notification submitted under subsection (h) that is effective."; and

(4) by striking the matter following paragraph (3) (as added by paragraph (3)) and inserting the following flush sentence:

"While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1)."

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

##### "Notification Relating to a Food Contact Substance

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the



Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

"(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

"(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

"(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

"(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

"(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

"(5)(A)(i) Except as provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless—

"(I) an appropriation equal to or exceeding the applicable amount under clause (iv) is made for such fiscal year for carrying out such program in such fiscal year; and

"(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

"(ii) The Secretary shall, not later than April 1, 1999, begin accepting and reviewing notifications submitted under the notification program established under this subsection if—

"(I) an appropriation equal to or exceeding the applicable amount under clause (iii) is made for the last six months of fiscal year 1999 for carrying out such program during such period; and

"(II) the Secretary certifies that the amount appropriated for such period for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals

or exceeds an amount equivalent to one-half the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

"(iii) For the last six months of fiscal year 1999, the applicable amount under this clause is \$1,500,000, or the amount specified in the budget request of the President for the six-month period involved for carrying out the notification program in fiscal year 1999, whichever is less.

"(iv) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is \$3,000,000, or the amount specified in the budget request of the President for the fiscal year involved for carrying out the notification program under this subsection, whichever is less.

"(B) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorization of appropriations is not effective for a fiscal year for any amount that is less than the applicable amount under clause (iii) or (iv) of subparagraph (A), whichever is applicable.

"(C) Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program established under this subsection for the next fiscal year.

"(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."

(3) in subsection (1), as so redesignated by paragraph (1), by adding at the end the following: "The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective."; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking "subsections (b) to (h)" and inserting "subsections (b) to (i)".

#### TITLE IV—GENERAL PROVISIONS

##### SEC. 401. DISSEMINATION OF INFORMATION ON NEW USES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after subchapter C the following:

##### "SUBCHAPTER D—DISSEMINATION OF TREATMENT INFORMATION

##### "SEC. 551. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS OR DEVICES.

"(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505, and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

"(1) a health care practitioner;

"(2) a pharmacy benefit manager;

"(3) a health insurance issuer;

"(4) a group health plan; or

"(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer meets the requirements of subsection (b).

"(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information under subsection (a) on a new use only if—

"(1)(A) in the case of a drug, there is in effect for the drug an application filed under subsection (b) or (j) of section 505 or a biologics license issued under section 351 of the Public Health Service Act, or

"(B) in the case of a device, the device is being commercially distributed in accordance

with a regulation under subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515;

"(2) the information meets the requirements of section 552;

"(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

"(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

"(A) a copy of the information to be disseminated; and

"(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

"(5) the manufacturer has complied with the requirements of section 554 (relating to a supplemental application for such use);

"(6) the manufacturer includes along with the information to be disseminated under this subsection—

"(A) a prominently displayed statement that discloses—

"(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

"(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

"(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

"(iv) the official labeling for the drug or device and all updates with respect to the labeling;

"(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

"(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

"(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

"(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

"(1) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

"(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug or device.

**"SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.**

"(a) **AUTHORIZED INFORMATION.**—A manufacturer may disseminate information under section 551 on a new use only if the information—

"(1) is in the form of an unabridged—  
 "(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 556(5)), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or  
 "(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; and  
 "(2) is not false or misleading and would not pose a significant risk to the public health.

"(b) **REFERENCE PUBLICATION.**—A reference publication referred to in subsection (a)(1)(B) is a publication that—  
 "(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;  
 "(2) has not been edited or significantly influenced by a such a manufacturer;  
 "(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;  
 "(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and  
 "(5) presents materials that are not false or misleading.

**"SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.**  
 "(a) **IN GENERAL.**—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary biannually—  
 "(1) a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer to a person described in section 551(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and  
 "(2) a list that identifies the categories of providers (as described in section 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).  
 "(b) **RECORDS.**—A manufacturer that disseminates information under section 551 shall keep records that may be used by the manufacturer when, pursuant to section 555, such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to such section. Such records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

**"SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.**  
 "(a) **IN GENERAL.**—A manufacturer may disseminate information under section 551 on a new use only if—  
 "(1)(A) the manufacturer has submitted to the Secretary a supplemental application for such use; or

"(B) the manufacturer meets the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application), or  
 "(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

"(b) **CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.**—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—  
 "(1) the studies needed for the submission of a supplemental application for the new use have been completed; and  
 "(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 551."

"(c) **CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.**—  
 "(1) **IN GENERAL.**—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—  
 "(A) the manufacturer has submitted to the Secretary an application containing—  
 "(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and  
 "(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and  
 "(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

"(2) **PROGRESS REPORTS ON STUDIES.**—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.  
 "(3) **EXTENSION OF TIME REGARDING PLANNED STUDIES.**—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if—  
 "(A) the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months; or  
 "(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

"(d) **EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.**—  
 "(1) **IN GENERAL.**—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—  
 "(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and  
 "(B)(i) the Secretary has approved the application in accordance with paragraph (2); or  
 "(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).  
 "(2) **CONDITIONS FOR APPROVAL.**—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B), as follows:

"(A) The Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to such drug or device for the manufacturer to incur the costs necessary for the submission of a supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—  
 "(i) the lack of the availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved; and  
 "(ii) the size of the population expected to benefit from approval of the supplemental application.

"(B) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

"(3) **TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.**—  
 "(A) **IN GENERAL.**—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.  
 "(B) **TERMINATION OF DEEMED APPROVAL.**—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval and under section 555(b)(3) order the manufacturer to cease disseminating the information.

"(e) **REQUIREMENTS REGARDING APPLICATIONS.**—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

**"SEC. 555. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.**

"(a) **POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.**—  
 "(1) **CORRECTIVE ACTIONS.**—With respect to data received by the Secretary after the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

"(2) **RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.**—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

"(b) **CESSATION OF DISSEMINATION.**—  
 "(1) **FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.**—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the

Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

"(2) **TERMINATION OF DEEMED APPROVAL.**—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval and under section 555(b)(3) order the manufacturer to cease disseminating the information.

"(e) **REQUIREMENTS REGARDING APPLICATIONS.**—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

**"SEC. 556. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.**

"(a) **POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.**—

"(1) **CORRECTIVE ACTIONS.**—With respect to data received by the Secretary after the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

"(2) **RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.**—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

"(b) **CESSATION OF DISSEMINATION.**—

"(1) **FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.**—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the



Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

"(2) **SUPPLEMENTAL APPLICATIONS.**—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if—

"(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval of the new use for which the application was submitted;

"(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer has not, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

"(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

"(3) **TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.**—If under section 554(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

"(c) **CORRECTIVE ACTIONS BY MANUFACTURERS.**—

"(1) **IN GENERAL.**—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

"(2) **TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.**—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

"SEC. 556. **DEFINITIONS.**

"For purposes of this subchapter:

"(1) The term 'health care practitioner' means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

"(2) The terms 'health insurance issuer' and 'group health plan' have the meaning given such terms under section 2791 of the Public Health Service Act.

"(3) The term 'manufacturer' means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

"(4) The term 'new use'—

"(A) with respect to a drug, means a use that is not included in the labeling of the approved drug; and

"(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

"(5) The term 'scientific or medical journal' means a scientific or medical publication—

"(A) that is published by an organization—

"(i) that has an editorial board;

"(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

"(iii) that has a publicly stated policy, to which the organization adheres, of full disclo-

sure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

"(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

"(C) that is generally recognized to be of national scope and reputation;

"(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

"(E) that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

"SEC. 557. **RULES OF CONSTRUCTION.**

"(a) **UNSOLICITED REQUEST.**—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

"(b) **DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.**—Notwithstanding subsection (a), (f), or (g) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or device, in accordance with section 551, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

"(c) **PATENT PROTECTION.**—Nothing in section 551 shall affect patent rights in any manner.

"(d) **AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.**—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 556(5)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles from such entity."

"(b) **PROHIBITED ACT.**—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

"(2) The dissemination of information in violation of section 551."

"(c) **REGULATIONS.**—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

"(d) **EFFECTIVE DATE.**—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

"(e) **SUNSET.**—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

"(f) **STUDIES AND REPORTS.**—

"(1) **GENERAL ACCOUNTING OFFICE.**—

"(A) **IN GENERAL.**—The Comptroller General of the United States shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this section, on the resources of the Department of Health and Human Services.

"(B) **REPORT.**—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study.

"(2) **DEPARTMENT OF HEALTH AND HUMAN SERVICES.**—

"(A) **IN GENERAL.**—In order to assist Congress in determining whether the provisions of such subchapter should be extended beyond the termination date specified in subsection (e), the Secretary of Health and Human Services shall,

in accordance with subparagraph (B), arrange for the conduct of a study of the scientific issues raised as a result of the enactment of such subchapter including issues relating to—

(i) the effectiveness of such subchapter with respect to the provision of useful scientific information to health care practitioners;

(ii) the quality of the information being disseminated pursuant to the provisions of such subchapter;

(iii) the quality and usefulness of the information provided, in accordance with such subchapter, by the Secretary or by the manufacturer at the request of the Secretary; and

(iv) the impact of such subchapter on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

"(3) **PROCEDURE FOR STUDY.**—

"(A) **IN GENERAL.**—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Comptroller General of the United States shall conduct such study.

"(B) **REPORT.**—Not later than September 30, 2005, the Institute of Medicine or the Comptroller General of the United States, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.

**SEC. 402. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES AND DIAGNOSTICS.**

Chapter V (21 U.S.C. 351 et seq.), as amended in section 401, is further amended by adding at the end the following:

"SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

"SEC. 561. **EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.**

"(a) **EMERGENCY SITUATIONS.**—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

"(b) **INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.**—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

"(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

"(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

"(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval, and

"(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

"(C) **TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.**—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an 'expanded access protocol'), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

"(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

"(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

"(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 505(i) or investigational device exemption in effect under section 520(g); or

"(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

"(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

"(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

"(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

"(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g), including regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

"(d) **TERMINATION.**—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or

investigational device if the requirements under this section are no longer met.

"(e) **DEFINITIONS.**—In this section, the terms 'investigational drug', 'investigational device', 'treatment investigational new drug application', and 'treatment investigational device exemption' shall have the meanings given the terms in regulations prescribed by the Secretary."

#### **SEC. 403. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.**

(a) **STANDARDS.**—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) **GUIDANCE TO INDUSTRY.**—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) **RESPONSIBILITIES OF CENTERS.**—The Secretary shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) **COLLABORATION.**—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

#### **SEC. 404. DISPUTE RESOLUTION.**

Subchapter E of chapter V, as added by section 402, is amended by adding at the end the following:

##### **"SEC. 503. DISPUTE RESOLUTION.**

"If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997."

#### **SEC. 405. INFORMAL AGENCY STATEMENTS.**

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

"(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

"(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

"(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

"(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

"(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

"(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

"(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

"(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents."

#### **SEC. 406. FOOD AND DRUG ADMINISTRATION MISSION AND ANNUAL REPORT.**

(a) **MISSION.**—Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (a) the following:

"(b) **MISSION.**—The Administration shall—

"(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

"(2) with respect to such products, protect the public health by ensuring that—

"(A) foods are safe, wholesome, sanitary, and properly labeled;

"(B) human and veterinary drugs are safe and effective;

"(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

"(D) cosmetics are safe and properly labeled; and

"(E) public health and safety are protected from electronic product radiation;

"(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

"(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products."

(b) **ANNUAL REPORT.**—Section 903 (21 U.S.C. 393), as amended by subsection (a), is further amended by adding at the end the following:

"(f) **AGENCY PLAN FOR STATUTORY COMPLIANCE.**—

"(1) **IN GENERAL.**—Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

"(2) **OBJECTIVES OF AGENCY PLAN.**—The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

"(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act;

"(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

"(C) implementing inspection and postmarket monitoring provisions of this Act;

"(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

"(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this Act for the review of all applications and submissions described in subparagraph (A) and submitted after the date of enactment of the Food and Drug Administration Modernization Act of 1997; and

"(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

"(g) **ANNUAL REPORT.**—The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

"(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

"(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

"(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy."

#### SEC. 407. INFORMATION SYSTEM.

(a) **AMENDMENT.**—Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SUBCHAPTER D—INFORMATION AND EDUCATION

#### "SEC. 741. INFORMATION SYSTEM.

"The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar

form of request) submitted to the Food and Drug Administration requesting agency action."

(b) **REPORT.**—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on the status of the system to be established under the amendment made by subsection (a), including the projected costs of the system and concerns about confidentiality.

#### SEC. 408. EDUCATION AND TRAINING.

(a) **FOOD AND DRUG ADMINISTRATION.**—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following section:

#### "SEC. 742. EDUCATION.

"(a) **IN GENERAL.**—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—

"(1) scientific training;

"(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;

"(3) training to achieve product specialization in such inspections; and

"(4) training in administrative process and procedure and integrity issues.

"(b) **INTRAMURAL FELLOWSHIPS AND OTHER TRAINING PROGRAMS.**—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians."

#### (b) **CENTERS FOR DISEASE CONTROL AND PREVENTION.**—

(1) **IN GENERAL.**—Part B of title III of the Public Health Service Act is amended by inserting after section 317F (42 U.S.C. 247b-7) the following:

#### "SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS.

"The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or non-appointment procedures."

(2) **EFFECTIVE DATE.**—The amendment made by this subsection is deemed to have taken effect July 1, 1995.

#### SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

#### "SEC. 906. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

"(a) **IN GENERAL.**—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

"(b) **REQUIRED ACTIVITIES.**—The activities referred to in subsection (a) are the following:

"(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

"(A) To increase awareness of—

"(i) new uses of drugs, biological products, and devices;

"(ii) ways to improve the effective use of drugs, biological products, and devices; and

"(iii) risks of new uses and risks of combinations of drugs and biological products.

"(B) To provide objective clinical information to the following individuals and entities:

"(i) Health care practitioners or other providers of health care goods or services.

"(ii) Pharmacy benefit managers.

"(iii) Health maintenance organizations or other managed health care organizations.

"(iv) Health care insurers or governmental agencies.

"(v) Consumers.

"(C) To improve the quality of health care while reducing the cost of health care through—

"(i) the appropriate use of drugs, biological products, or devices; and

"(ii) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

"(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.

"(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

"(c) **APPLICATION FOR GRANT.**—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(d) **PEER REVIEW.**—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

"(e) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 1998, and \$3,000,000 for each of fiscal years 1999 through 2002."

#### SEC. 410. MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION.

(a) **GOOD MANUFACTURING PRACTICE REQUIREMENTS.**—Section 520(f)(1)(B) (21 U.S.C. 360f(f)(1)(B)) is amended—

(1) in clause (i), by striking ", and" at the end and inserting a semicolon;

(2) in clause (ii), by striking the period and inserting "; and"; and

(3) by inserting after clause (ii) the following:

"(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices."

(b) **HARMONIZATION EFFORTS.**—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

"(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.

"(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

"(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on

methods and approaches to harmonize regulatory requirements.

"(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

"(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff)."

#### SEC. 411. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

##### "SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

#### "SEC. 746. ENVIRONMENTAL IMPACT.

"Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C))."

#### SEC. 412. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS AND COSMETICS.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 411, is further amended by adding at the end the following:

##### "SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

#### "SEC. 751. NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS.

"(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

"(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

##### "(b) EXEMPTION.—

"(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

"(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

"(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

"(C) would not unduly burden interstate commerce.

"(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

##### "(c) SCOPE.—

"(1) IN GENERAL.—This section shall not apply to—

"(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

"(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

##### "(d) EXCEPTIONS.—

"(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

"(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

"(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of the Food and Drug Administration Modernization Act of 1997.

"(2) STATE INITIATIVES.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

"(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act."

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking "prescription drugs" each place it appears and inserting "prescription drugs, nonprescription drugs intended for human use."

(c) MISBRANDING.—Subparagraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

"(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

"(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

"(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

"(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause

with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

"(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

#### "SEC. 752. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

"(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

"(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

"(1) protects an important public interest that would otherwise be unprotected;

"(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

"(3) would not unduly burden interstate commerce.

"(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

"(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

"(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997."

#### SEC. 413. FOOD AND DRUG ADMINISTRATION STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) LIST AND ANALYSIS.—The Secretary of Health and Human Services shall, acting through the Food and Drug Administration—

(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of enactment of the Food and Drug Administration Modernization Act of 1997 and shall provide the analysis required by paragraph (2) within 2 years after such date of enactment.

(b) STUDY.—The Secretary of Health and Human Services, acting through the Food and

Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

**(c) STUDY OF MERCURY SALES.—**

**(1) STUDY.**—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

**(A)** the scope of mercury use as a drug or dietary supplement; and

**(B)** the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

**(2) REGULATIONS.**—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

**SEC. 414. INTERAGENCY COLLABORATION.**

Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

**“(c) INTERAGENCY COLLABORATION.**—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.”

**SEC. 415. CONTRACTS FOR EXPERT REVIEW.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

**“SEC. 907. CONTRACTS FOR EXPERT REVIEW.**

**“(a) IN GENERAL.—**

**“(1) AUTHORITY.**—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

**“(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.**—The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or

submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

**“(b) REVIEW OF EXPERT REVIEW.—**

**“(1) IN GENERAL.**—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

**“(2) LIMITATION.**—A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).”

**SEC. 416. PRODUCT CLASSIFICATION.**

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

**“SEC. 565. CLASSIFICATION OF PRODUCTS.**

**“(a) REQUEST.**—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

**“(b) STATEMENT.**—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

**“(c) INACTION OF SECRETARY.**—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.”

**SEC. 417. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

**“(i)(1)** Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

**“(2)** The establishment shall also provide the information required by subsection (j).

**“(3)** The Secretary is authorized to enter into cooperative arrangements with officials of for-

foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).”

**SEC. 418. CLARIFICATION OF SEIZURE AUTHORITY.**

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

**(1)** in the fifth sentence, by striking “paragraphs (1) and (2) of section 801(e)” and inserting “subparagraphs (A) and (B) of section 801(e)(1)”; and

**(2)** by inserting after the fifth sentence the following: “Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.”

**SEC. 419. INTERSTATE COMMERCE.**

Section 709 (21 U.S.C. 379a) is amended by striking “a device” and inserting “a device, food, drug, or cosmetic”.

**SEC. 420. SAFETY REPORT DISCLAIMERS.**

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

**“SUBCHAPTER G—SAFETY REPORTS**

**“SEC. 756. SAFETY REPORT DISCLAIMERS.**

“With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.”

**SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.**

Section 301 (21 U.S.C. 331) is amended by striking paragraph (1).

**SEC. 422. RULE OF CONSTRUCTION.**

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

**TITLE V—EFFECTIVE DATE**

**SEC. 501. EFFECTIVE DATE.**

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125 and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same

That the House recede from its amendment to the title of the bill.

TOM BLILEY,  
MICHAEL BILIRAKIS,  
JOE BARTON.



JAMES GREENWOOD,  
RICHARD BURR,  
ED WHITFIELD,  
JOHN D. DINGELL,  
SHERROD BROWN,  
HENRY A. WAXMAN,  
RON KLINK,

*Managers of the Part of the House.*

JIM JEFFORDS,  
DAN COATS,  
JUDD GREGG,  
BILL FRIST,  
MIKE DEWINE,  
EDWARD M. KENNEDY,  
CHRISTOPHER DODD,  
TOM HARKIN,  
BARBARA A. MIKULSKI,

*Managers on the Part of the Senate.*

#### JOINT EXPLANATORY STATEMENT OF THE COMMITTEE OF CONFERENCE

The managers on the part of the House and the Senate at the conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, submit the following joint statement to the House and the Senate in explanation of the effect of the action agreed upon by the managers and recommended in the accompanying conference report:

The House amendment to the text of the bill struck all of the Senate bill after the enacting clause and inserted a substitute text.

The Senate recedes from its disagreement to the amendment of the House with an amendment that is substitute for the Senate bill and the House amendment. The differences between the Senate bill, the House amendment, and the substitute agreed to in conference are noted below, except for clerical corrections, conforming changes made necessary by agreements reached by the conferees, and minor drafting and clerical changes.

The conference agreement on S. 830, the Food and Drug Administration Modernization Act of 1997, provides for (1) the reauthorization of the Prescription Drug User Fee Act of 1992; (2) the improvement of regulation of drugs through such reforms as those pertaining to pediatric studies of drugs, procedures relating to fast track drugs, health care economic information, national uniformity for over-the-counter drugs and cosmetics, and data requirements for drugs and biological products; (3) the improvement of regulation of medical devices through such reforms as those pertaining to device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, and accredited party review; (4) the improvement of regulation of food through such reforms as those pertaining to the timetable and regulatory authority of the Secretary in processing health and nutrient content claims, food contact substance notifications, and information relating to irradiation treatment; and (5) general provisions pertaining to the dissemination of information, expanded access to investigational therapies, and consumer access to information about clinical trials of investigational therapies.

Certain matters agreed to in conference are noted below:

#### TITLE I—IMPROVING REGULATION OF DRUGS Prescription Drug User Fee Act (Subtitle A)

The conferees believe it is important to place the PDUFA reauthorization provisions of the Act in the overall context of the budgetary agreements which have been put into place by the 1997 Balanced Budget Agree-

ments (BBA). This Act preserves the original PDUFA adjustment factor and therefore the basic understanding behind the 1992 enactment of this provision: that is, the industry willingness to pay user fees for enhanced performance in the drug approval process. Nevertheless the conferees acknowledge that the 1997 BBA places tight constraints on the appropriations process, particularly in the out years. The conferees expect the appropriators will make every effort to meet the trigger so that FDA is allowed to collect and expend user fees. However, it must be acknowledged that particularly in the fifth year of BBA, budgetary pressures on all discretionary spending will be great.

Breakdowns of the actual spending levels at FDA have not traditionally been provided to the appropriators, making it difficult to conduct oversight. Beginning in Fiscal Year 1998, appropriators will require FDA to submit a directed operating budget as part of the annual budget request. This will serve as a functional breakdown of how appropriated dollars are spent, similar to the report FDA submits annually to show how the agency spent collected PDUFA user fees.

The conferees expect the President's budgetary request for FDA for salaries and expenses to meet the PDUFA levels specified for each of these years and not be based on any assumption of the enactment of new substitutive user fees on other FDA regulated industries.

#### Pediatric studies of drugs (Sec. 111)

The conference agreement provides that if the Secretary determines that information about a drug may produce health benefits in a pediatric population and makes a written request for pediatric studies (including a time frame for completing the studies), and the studies are completed and are accepted by the Secretary, then the sponsor or manufacturer will qualify for 6 months of extra market exclusivity. The agreement authorizes the Secretary to determine the time frame for completing the studies, but the conferees emphasize that such studies should be sought, conducted, and completed at the earliest possible opportunity. The conferees do not intend that such studies be artificially timed for market advantage.

The agreement provides that no new market exclusivity may be applied to any new drug for which a new drug application is submitted after January 1, 2002. However, the agreement provides a continuation of the program for certain drugs already on the market on the date of enactment. The purpose of this limited extension is to ensure that, with respect to such already marketed drugs, exclusivity remains available if the Secretary determines there is a continuing need for additional information relating to the use of such drugs that may promote health benefits in the pediatric population. This is applicable only to drugs already included on the list under subsection (b) as of January 1, 2002. The Secretary will not list any additional drugs under Section 505A(b) after January 1, 2002. These drugs will be eligible for the applicable 6-month time extension if the requested studies satisfy all requirements of the section.

The conferees expect the Secretary to consult with experts in pediatric research to develop the list of drugs under subsection (b), and to set priorities for studies on these drugs. Such experts should include representatives from the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit (PPRU) Network, and the U.S. Pharmacopeia. The conferees note particularly the excellent efforts of NIH, especially through the PPRU Network, which will contribute significantly to this effort.

The conference agreement also requires that a study be conducted on the program,

by January 1, 2001, that reviews all aspects of the program, including its impact on the price and availability of drugs and the availability of generic drugs.

With respect to any requested studies under this provision, the conferees intend that data collected prior to a request or requirement by the Secretary may be used, in addition to data collected after such request or requirement in satisfying the provisions of this section.

#### Clinical investigations (Sec. 115)

The conferees note that the requirement for the Secretary to review existing guidance and develop additional guidance, as appropriate, on the inclusion of women and minorities in clinical trials does not require participation of women and minorities in any particular trial. Furthermore, FDA is required to consult with the National Institutes of Health, which has developed inclusion guidelines for subjects in federally funded clinical research, and with representatives of the drug manufacturing industry, to ensure that ethical, scientific, and legal issues specific to privately funded clinical research are considered. The conferees expect FDA to set forth its general policy regarding: the inclusion of women and minorities in drug development research; population-specific analyses of clinical data and assessment of potential pharmacokinetic differences; and the conduct of specific additional studies in women or minorities, where appropriate.

#### Content and review of applications (Sec. 119)

The Secretary is required to meet with an applicant if the applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of studies, if the sponsor provides the information necessary to discuss and reach agreement on the design and size of such studies. The Secretary may refuse to meet if the sponsor does not provide such information or if the Secretary determines that such meeting is premature or would not be useful.

#### Positron emission tomography (Sec. 121)

The conference agreement provides for regulation of positron emission tomography (PET) drugs and replaces earlier industry guidance and regulatory standards for PET products promulgated by the FDA. The agreement provides that, until the Secretary establishes procedures under subsection (c)(1) described below, neither a New Drug Application (NDA) nor an Abbreviated New Drug Application (ANDA) is required by a licensed practitioner to produce a compounded PET product in accordance with United States Pharmacopeia (USP) standards.

The agreement requires the Secretary, in two years to establish procedures for approving PET products, including compounded PET products, and good manufacturing practices for such products, taking account of relevant differences between commercial manufacturers and non-profit organizations and in consultation with patient groups, physicians, and others. The Secretary may not require NDAs or ANDAs for these products for four years (or two years after the procedures mentioned above are established).

A compounded PET drug, by definition, must be compounded pursuant to a valid prescription order and in accordance with state law, among other requirements. A PET drug that fails to meet these requirements is not a "compounded PET drug" and therefore is not exempt from section 501(a)(2)(B) (21 USC 351(a)(2)(B)) or from subsections (b) and (j) of section 505 (21 USC 355). PET drugs that fail to meet the definition of a "compounded PET drug" shall be subject to the procedures and requirements established by the Secretary under subsection (c)(1).

*Application of Federal law to practice of pharmacy compounding (Sec. 127)*

The conference report includes provisions of pharmacy compounding that reflect the conferees' extensive work with the Food and Drug Administration and other interested parties to reach consensus. It is the intent of the conferees to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is appropriate and lawful. The conditions set forth in Section 503A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations.

The conferees intend that, as defined in subparagraph (b)(2), copies of commercially available drug products do not include drug products in which the change from the commercially available drug product produces a "significant difference" for the particular patient. For example, the removal of a dye from a commercially available drug product for a particular patient who is allergic to such dye shall be presumed to be a "significant difference." The conferees expect that FDA and the courts will accord great deference to the licensed prescriber's judgment in determining whether the change produces a "significant difference." However, where it is readily apparent, based on the circumstances, the "significant difference" is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09% are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescription for compounded products.

The conferees also expect that the Secretary will develop the list of bulk drug substances described in subsection (b)(1)(A)(i)(III) within one year from the date of enactment. It is the intent of the conferees that the criteria used to develop the list of bulk drug substances and the list itself are to be developed in consultation with the United States Pharmacopoeia. The conferees further intend that where evidence relating to an approval under Section 505 does not exist, the Secretary shall consider other criteria. Finally, the conferees intend that after this list is published, organizations may petition the FDA for inclusion of additional substances on the aforementioned list.

The memorandum of understanding described in Paragraph (b)(3)(B)(i) shall provide guidance on the meaning of inordinate amounts, including any circumstances under which the compounding of drug products for interstate shipment in excess of 5 percent of total prescription order would be included in a "safe harbor" of interstate shipments of compounded products that shall not be deemed inordinate.

As stated in paragraph (e), nothing in Section 503A is intended to change or otherwise affect current law with respect to radiopharmaceuticals, including PET drugs. Further, as stated in paragraph (f), the term compounding does not include mixing reconstituting or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufac-

turer directions consistent with that labeling. Nothing in this provision is intended to change or otherwise affect the Act with respect to reconstitution or other similar processing that is done pursuant to a manufacturer's approved labeling, and other directions from such manufacturer that are consistent with that labeling. In general, such practices, as performed by a licensed practitioner for an identified individual patient, are appropriately regulated by state boards of pharmacy. The conferees intend that facilities required to register with the FDA, including those which are engaged in non-patient specific compounding and reconstitution activities, are appropriately regulated under the Federal Food, Drug and Cosmetic Act.

Finally, with regard to the effective date described in paragraph (b), the conferees expect the FDA to work diligently to consult with necessary parties to promulgate the required regulations and lists. Nothing in paragraph (b) is intended to abrogate the Secretary's responsibility to promulgate such regulations through the notice and comment rulemaking process.

*Reauthorization of the Clinical Pharmacology Program (Sec. 128)*

The conference agreement extends through fiscal year 2002 the authorization of appropriations of the Clinical Pharmacology Training Program, a program originally authorized under section 2(b) of P.L. 102-222. Nothing in this section of the agreement prohibits the Secretary from continuing the awarding of grants to the original and current grantees. The conferees strongly recommend that the Secretary continue the development of the clinical pharmacology programs at the colleges and universities originally selected to participate in the program.

*Regulations for sunscreen products (Sec. 129)*

The conference agreement includes a provision requiring FDA to continue diligently with its work to complete its rulemaking process on sunscreen products and to issue regulations within 18 months. The conferees recognize that various technical and scientific issues may take longer to resolve than other aspects of the rulemaking. The conferees do not intend that all regulation in this area be complete or comprehensive by a specified date.

**TITLE II—IMPROVING REGULATION OF DEVICES**  
*Scope of review (Sec. 205)*

The conference agreement addresses the issue of regulatory burden by ensuring that the impact of the Secretary's necessary review, approval, and oversight functions is not inappropriate. This assurance is achieved by requiring the Secretary to consider, in consultation with an applicant for device approval, the method for evaluating the device's effectiveness that would be appropriate, least burdensome, and reasonably likely to result in the device's approval. The conferees believe that this language is necessary to and consistent with improving communications between the FDA and regulated persons, increasing regulatory efficiency, and decreasing the length of product review and approval.

*Premature notification (Sec. 206)*

The conference agreement exempts class I devices from premarket notification under section 510(k), except those types that present a potential unreasonable risk of illness or injury, or that are of substantial importance in preventing impairment of human health. The agreement also requires the Secretary to publish a notice listing the types of class II devices that are exempt from premarket notification. The Secretary must publish this initial list within 60 days.

Thereafter, class II devices may be exempted by the Secretary on the Secretary's own initiative or through a petition process. The agreement provides that the Secretary must respond to any such petition within 180 days or the petition will be deemed granted.

The conferees do not intend by this provision that the Secretary should up-classify low-risk class I device in order to avoid exempting them. The conferees believe the appropriate exemption of class I and certain class II devices will allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices. Focusing resources in this manner will ensure the public continues to be adequately protected and will still benefit from the earlier availability of new products.

*Accredited party review (Sec. 210)*

The conference agreement makes modifications to the House and Senate provisions establishing the process by which the Secretary will accredit person to review and initially classify 510(k) devices. The agreement's provisions relating to the scope and the duration of the pilot program specify that an accredited person may not review a class III device, a class II device that is permanently implantable, life-sustaining or life-supporting, or a class II device for which clinical data are required. The latter category is limited in size to not more than six percent of all 510(k) submissions. In addition, the agreement provides for the termination of the pilot program after the Secretary has met specified targets for inclusion of eligible devices.

*Reports (Sec. 213)*

The conference agreement amends Section 519 of the Federal Food, Drug and Cosmetic Act to reduce the reporting requirements for device distributors. Manufacturers and importers, however, are required to comply with the existing requirements for medical device reporting. The amendment to section 519(a)(9) requires distributors to keep records and make them available to the Secretary on request. Because distributors will no longer be submitting reports to the Secretary, copies of reports would also not be sent to the manufacturers. This is not intended to provide the FDA with any new statutory authority to require distributors to keep additional records; it merely clarifies that existing record keeping requirements of section 519(a) continue to apply. This provision also removes the registration, listing, and reporting requirements for distributors under section 510. Since user facilities and manufacturers submit medical device reports to the FDA, there is no need for additional reporting by distributors. The FDA is urged to allow all record keeping, including distributor record keeping, to be accomplished through either electronic means or written documentation. The FDA is also urged to revise its current regulations on distributor record keeping (21 C.F.R. §804.35(b)) to provide that distributors need only keep records of complaints for six years from the date a complaint is received by the distributor, consistent with the longest statutes of limitations under State tort laws. Currently, FDA regulations require distributors to keep records for two years from the date of the record of complaint or the expected life of the device, whichever is greater. It is the intent of the conferees to simplify these requirements, since distributors, unlike manufacturers, are not able to determine the expected life of a device. Since these records will be kept by manufacturers as well, it is unnecessarily burdensome for distributors to keep these records for other than a fixed period of time.

The conferees expect the FDA to modify its regulations under Sec. 519(f) to ensure



that the reports under this section are not required from any manufacturer, importer, or distributor who also is regulated and required to make such reports under the Radiation Control for Health and Safety Act of 1968 (21 U.S.C. 36011).

*Practice of medicine (Sec. 214)*

The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere in the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA. It is the intent of the conferees that this provision not be construed to affect medical professional liability.

**TITLE III—IMPROVING REGULATION OF FOOD**

*Flexibility for regulations regarding claims (Sec. 301)*

The conference agreement clarifies the parameters within which the Secretary may use the interim final rulemaking authority established under this section. This authority enables the Secretary to make proposed regulations on claims effective upon publication, pending consideration of public comment and publication of a final regulation. The conferees' clarifying language emphasizes that this authority may be used when the Secretary determines that it is necessary to enable the Secretary to improve consumer access to important dietary information and to ban or modify a claim in a prompt fashion. The conferees' intent in creating this expedited rulemaking authority for health and nutrient content claims is that it be used primarily to expedite the review of petitions for health and nutrient content claims based on authoritative statements.

*Health and nutrient content claims (Secs. 303, 304)*

The conference agreement makes streamlined procedures available for the Secretary to permit more scientifically sound nutrition information to be provided to consumers through health and nutrient content claims. This process is triggered by authoritative statements of entities such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and the National Academy of Sciences (NAS). Although the provision specifically permits claims to be made on the basis of a statement produced by subsidiaries of NAS, the conferees intend that the lack of similar language with respect to entities such as NIH and CDC be interpreted as a reflection of the desire of the conferees that statements issued by entities such as NIH and CDC reflect consensus within those institutions. The agreement makes minor modifications to the House provisions on health and nutrient content claims to expedite the process by which such claims are processed. As part of the submissions to the Secretary for health claims based on authoritative statements, a balanced representation of the scientific literature may include a bibliography of such literature.

*Disclosure of irradiation (Sec. 306)*

The conference agreement ensures that no existing provision of the Federal Food Drug and Cosmetic Act will be considered to require a separate radiation disclosure statement that is more prominent than the declaration of ingredients on the food label. To ensure the intended effect of this provision, the conferees direct the Secretary promptly to publish for public comment proposed amendments to current regulations relating to the labeling of foods treated with ionizing radiation. The conferees expect final regula-

tions to be issued not more than 12 months after the date of enactment of this measure. The public comment process should be utilized by the Secretary to provide an opportunity to comment on whether the regulations should be amended to revise the prescribed nomenclature for the labeling of irradiated foods and on whether such labeling requirements should expire at a specified date in the future. The conferees intend for any required disclosure to be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety.

*Food contact substances (Sec. 309)*

The conference agreement establishes a notification process for the regulation of components of food packaging, known as food contact substances, which is intended to expedite authorization of the marketing of a food contact substance except where the Secretary determines that submission and review of a food additive petition is necessary to provide adequate determination of safety. The agreement also authorizes appropriations to finance the costs of the new notification process. To protect the Agency from having to reallocate resources within CFSAN to meet the costs of implementation, the agreement provides that implementation is to be triggered only when the FDA receives an appropriation sufficient to fund the program. The conferees strongly encourage the House and Senate to appropriate the funds authorized. The conferees also urge the Committees of jurisdiction, when reauthorizing the notification program, to reevaluate fully its operational effectiveness, the appropriateness of its timeframes, the adequacy of funding, and its protection of the public health.

On the subject of food contact substances, the conferees wish to commend the FDA and the Environmental Protection Agency (EPA) for developing an Administration policy on the question of returning from EPA to FDA regulatory authority over antimicrobials used as food contact substances. This policy addresses the uncertainty unintentionally created by the Food Quality Protection Act of 1996 (FQPA) over the authority for regulating antimicrobials used as food contact substances. Although the legislative language effecting this policy was considered by the conferees to be outside the scope of this conference, the conferees acknowledge the significant need for this change and urge FDA and EPA to continue to work with the Congress to identify and develop an appropriate and expeditious vehicle for action on this matter. In the interim, the conferees urge the agencies not to delay active review of pending petitions and the pursuit of the most immediate means to achieve resolution of this jurisdictional issue.

**TITLE IV—GENERAL PROVISIONS**

*Dissemination of treatment information (Sec. 401)*

The conference agreement's inclusion of this section is intended to provide that health care practitioners can obtain important scientific information about uses that are not included in the approved labeling of drugs, biological products, and devices. The conferees also wish to encourage that these new uses be included on the product label. Therefore, the agreement includes strong incentives to conduct the research needed and file a supplemental application for such uses. A manufacturer who seeks to disseminate information about a new use must either certify that it will file a supplemental application or must submit a proposed protocol and schedule for conducting the necessary studies and a certification that a supplemental application will be filed.

Although the conferees intend to ensure that the research is undertaken to get new uses on product labels, the conferees also recognize that there may be limited circumstances when it is appropriate to exempt a manufacturer from the requirement to file a supplemental application. In making the determination of whether to grant an exemption pursuant to subsection (d)(2), the Secretary may consider, among other factors, whether: the new use meets the requirements of section 186(t)(2)(B) of the Social Security Act; a medical specialty society that is represented in or recognized by the Council of Medical Specialty Societies (or is a subspecialty of such society) or is recognized by the American Osteopathic Association, has found that the new use is consistent with sound medical practice; the new use is described in a recommendation or medical practice guideline of a Federal health agency, including the National Institutes of Health, the Agency for Health Care Policy Research and the Centers for Disease Control and Prevention of the Department of Health and Human Services; the new use is described in one of three compendia: The U.S. Pharmacopeia-Drug Information, the American Medical Association Drug Evaluation, or the American Hospital Association Formulary Service Drug Information; the new use involves a combination of products of more than one sponsor of a new drug application, a biological license application, a device premarket notification, or a device premarket approval application; or the patent status of the product.

The conferees recognize that there may be cases where the size of the patient population may be cause for the Secretary to determine that a supplemental application should not be filed. However, this is intended to be the exception, rather than the rule, in the case of populations suffering from orphan or rare disorders. For many years, this Congress has sought to encourage research into orphan diseases and the approval of innovative drugs for their treatment. The Secretary should examine very carefully whether an exemption from filing a supplemental application might hinder such research and recognize the vital importance of encouraging application for new drugs and new drug uses intended to treat rare disorders.

*Expanded access to investigational therapies and diagnostics (Sec. 402)*

The conference report provides statutory direction to expand access programs and emphasizes that opportunities to participate in expanded access programs are available to every individual with a life-threatening or seriously debilitating illness for which there is not an effective, approved therapy. The conferees note that they purposely used broad language in this section relating to "serious" conditions, without attempting to define them, in order to permit wide flexibility in implementation. Illnesses that do not cause death, or imminent death, can nonetheless destroy the lives of both patients and their families. The conferees therefore intend that the seriousness of an illness be given broad consideration, to take into account all of the circumstances involved.

Currently, Federal law allows drug companies to make experimental drugs available, under specific circumstances, to seriously and terminally ill patients. However, companies are often reluctant to do so because they fear that inclusion of data on such very ill patients will jeopardize the approval of their product because these patients' medical progress on any therapy may conflict with or be inconsistent with data from patients in the clinical studies. The conferees request that the FDA evaluate ways to address this problem, particularly for terminal

patients who have failed existing approved therapies.

*Information system (Sec. 407)*

The conferees intend that the information system shall provide access to the information by the applicant under conditions set by the Secretary, except that access shall not be provided under any particular form of information system to any applicant until appropriate safeguards are in place to ensure that integrity and confidentiality of the information for which access is provided.

*Education and training (Sec. 408)*

The conference agreement authorizes the Centers of the FDA that conduct intramural research to provide fellowships and training to appropriate undergraduate, pre-doctoral, and/or post-doctoral candidates. In the past, FDA's Centers provided for a limited number of scientific training positions through Full Time Equivalent programs or interagency agreements with other federal agencies which have the statutory authority to hire trainees through third parties. However, many of the benefits of the training program have been reduced because FDA has not had specific direct authority to conduct and support them. In light of the additional overhead costs, reduced training flexibility, increased paperwork, and hiring delays that have resulted, it is increasingly difficult and impractical for FDA to hire trainees as FTE Service Fellows. As a result, the Intramural Research and Training Authority authorized here is intended to provide the FDA the authority to conduct and support directly the selection and training of fellows, allow more efficient use of appropriated funds by reducing overhead and other costs, and permit the training of such candidates as non-FTE positions. The conference agreement also provides similar authority for the Centers for Disease Control and Prevention.

*Centers for education and research on therapeutics (Sec. 409)*

The conference agreement establishes a demonstration program to conduct research and increase awareness of new products and ways to improve their effective use, and to increase awareness of risks of both new uses and combinations of therapies. In carrying out this demonstration program, the Secretary is directed to act through the Agency for Health Care Policy and Research (AHCPR) in consultation with the FDA Commissioner. The conferees designated AHCPR as the lead agency because of its expertise in the evaluation of the effectiveness of clinical care, its non-regulatory role, and its close working relationship with the health care community in the improvement of the quality of care. Accordingly, this section establishes a new Section 928 in Title IX of the Public Health Service Act, the authorizing statute for AHCPR.

To ensure appropriate coordination and to avoid unnecessary duplication, AHCPR is required to consult closely with the FDA in the development and operation of this demonstration program. The conferees expanded the focus of this demonstration to include ways to improve the effective use of drugs, biological products, and devices as well as risks of new combinations of such products and directed that the clinical information gained in the project would be provided to consumers as well as health care practitioners and insurers. Finally, the conferees direct AHCPR also to consider the appropriate use of products in meeting the purposes of this section.

*Environmental impact review (Sec. 411)*

The conferees believe that FDA's new procedures implementing the National Environmental Policy Act (NEPA) appropriately eliminate unnecessary paperwork and delays

associated with prior agency practices. Section 411 makes clear that an environmental impact statement (EIS) prepared in accordance with those regulations will meet the requirements of NEPA. The conferees do not intend this section to preclude judicial review of EISs. The conferees understand that the FDA may modify its regulations periodically, in consultation with the Council on Environmental Quality and the FDA's authorizing committees, as new circumstances or information warrants.

Because the Clean Air Act authorizes production of limited quantities of Class I and Class II substances for use in medical devices, there will be a continuing, but limited, supply of these substances. The EPA shall not dictate, promote or otherwise encourage a policy preference for disposal by incineration of the contents of metered-dose inhalers, but instead allow such contents to be recaptured, recycled or reused consistent with section 608(a)(3) of the Clean Air Act until such time that Congress conducts oversight hearings into the issue.

*National uniformity for nonprescription drugs and cosmetics (Sec. 412)*

*Confidentiality of OTC company self-audits*

Public policy should encourage drug manufacturers to conduct audits of their activities to candidly alert management to potential problems so that they can be addressed quickly and effectively. If FDA were to assert routine access to these audits, it would create serious disincentives to conducting appropriate audits and preparing thorough reports of the results. FDA already has a policy of not ordinarily requesting audit reports, which is set forth in compliance policy guide (#7151.02, Sec. 130.300) that applies to prescription drug firms. It is expected that OTC drug firms would be subject to the same compliance policy guide. Thus, during routine inspections of OTC drug establishments, FDA would not be expected to request or to review or copy reports and records that result from the firm's own audits and inspections of its operations to assure compliance with applicable FDA requirements such as good manufacturing practice (GMP) regulations. FDA would reserve the right to review such audits in certain limited circumstances as outlined in the compliance guide.

*OTC and cosmetics inspection*

The conferees intend that FDA exercise its new records inspection authority fairly and carefully, especially with regard to inspections at facilities that manufacture products that are both cosmetics and over-the-counter drugs. Cosmetic products that are also OTC drugs will, under the provisions of this bill, benefit from full national uniformity relating to all regulatory requirements, including those associated with ingredients, labeling, and packaging. Therefore, under these provisions, manufacturers of such OTC products will be subject to records inspection by FDA. The conferees want to make clear that any records inspection applies only to those products for which there is full national uniformity. This new records inspection authority applies only to products determined to be over-the-counter drugs. It does not apply to products that are solely cosmetics.

In the case of an inspection at a facility which deals both with cosmetic products that are OTC drugs and those that are not, FDA inspectors do not have access to any records relating to the cosmetic products. Further, the conferees want to make clear that there is no records inspection authority under these provisions for facilities dealing exclusively with cosmetics.

Finally, the conferees expect that FDA will provide sufficient time and guidance to the over-the-counter drug industry prior to

initiating any program of records inspection and in the early stages of implementing this new requirement.

*Effect of national uniformity on state enforcement "little FTC" laws*

All states have laws prohibiting false and misleading advertising, modeled on the Federal Trade Commission Act. These laws have been applied to prohibit unsubstantiated claims for nonprescription drugs and cosmetics, and to require corrective advertising. This provision is not intended to preempt the application of these laws under such circumstances.

The Conference Committee intends to make clear that "Little FTC" laws, as they have historically been written and applied, are not preempted. The scope of national uniformity is modified to only apply to state requirements that relate to labeling and packaging or, if they go beyond labeling and packaging, to requirements relating to warnings. Thus, advertising issues relating to claims substantiation, fair balance, and misleading or deceptive claims are outside the scope of preemption.

*Effect of national uniformity on state food labeling laws*

This provision is not intended to preempt or prohibit States from regulating the labeling of food which derives from animals treated with non-prescription drugs. Nor are these provisions intended to void State regulations on the use of these drugs.

*Product classification (Sec. 416)*

Subsections (b) and (c) have been amended to make clear that FDA may only modify product classifications for public health reasons based on scientific information.

TOM BLILEY,  
MICHAEL BILIRAKIS,  
JOE BARTON,  
JAMES GREENWOOD,  
RICHARD BURR,  
ED WHITFIELD,  
JOHN D. DINGELL,  
SHERROD BROWN,  
HENRY A. WAXMAN,  
RON KLING.

*Managers on the Part of the House.*

JIM JEFFORDS,  
DAN COATS,  
JUDD GREGG,  
BILL FRIST,  
MIKE DEWINE,  
EDWARD M. KENNEDY,  
CHRISTOPHER DODD,  
TOM HARKIN,  
BARBARA A. MIKULSKI.

*Managers on the Part of the Senate.*

**LEAVE OF ABSENCE**

By unanimous consent, leave of absence was granted to:

Mr. UNDERWOOD (at the request of Mr. GEPHARDT) for today and the balance of the week, on account of official business.

Mr. YATES (at the request of Mr. GEPHARDT) for November 8 after 12 noon and November 9, on account of personal reasons.

**SENATE BILLS AND CONCURRENT RESOLUTION REFERRED**

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 508. An act to provide for the relief of Mai Hoa "Jasmin" Salehi; to the Committee on the Judiciary.

Massiah-Jackson, for the eastern district of Pennsylvania, Federal court. Judge Massiah-Jackson has a very distinguished record on the State Court of Common Pleas in Philadelphia County. Although some questions have arisen, a couple of intemperate remarks, I think, do not disqualify her. If intemperate remarks were disqualifiers, there wouldn't be any Federal judges, there wouldn't be any Senators or anybody in any other positions. Questions have arisen about her sentencing. Out of 4,000 cases, 95 appeals were taken and reversals in only 14 cases. I urge my colleagues to support Judge Frederica Massiah-Jackson so we can fill a vacancy on the Federal court.

Several Senators addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

#### UNANIMOUS-CONSENT AGREEMENT—CONFERENCE REPORT ACCOMPANYING S. 830

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate now turn to the conference report accompanying the FDA reform bill; that it be considered as having been read; that there be 30 minutes for debate equally divided between the chairman and ranking minority member, with an additional 5 minutes for Senator REED of Rhode Island; and that following the conclusion or yielding back of time, the Senate proceed to vote on the adoption of the conference report, all without further action or debate.

The PRESIDING OFFICER. Is there objection?

Mr. HARKIN. Reserving the right to object.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. HARKIN. As I understand this, we now have an hour of debate?

Mr. JEFFORDS. Half hour; 30 minutes.

Mr. HARKIN. And then we will vote.

Mr. JEFFORDS. Right.

Mr. HARKIN. It will be a recorded vote.

Mr. JEFFORDS. No, it will not be. It depends on the body, but it is intended to be a voice vote.

Mr. HARKIN. Thirty minutes of debate, a voice vote and then there will be no pending business after that? What will the pending business be after that voice vote?

The PRESIDING OFFICER. The pending business is the fast-track bill. My understanding of the request of the Senator from Vermont was 30 minutes equally divided, plus an additional 5 minutes for the Senator from Rhode Island.

Mr. HARKIN. Mr. President, since everybody else seems to be getting in line, I wonder if I can amend that to ask unanimous consent that after the disposition of this bill, after the voice vote, which I understand is included in your disposition, after the disposition of this bill, that the Senator from Iowa be recognized.

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Mr. President, I was wondering if we could ask for 40 minutes. I have a couple of Senators on our side who would like time, who have been very active on this issue. Perhaps we could have a few more minutes so that we could accommodate their requests. Would that be agreeable?

Mr. JEFFORDS. Does that include the Senator from Iowa?

Mr. HARKIN. No.

Mr. KENNEDY. No.

Mr. JEFFORDS. Yes. I have an objection to the request from the Senator from Iowa.

Mr. KENNEDY. Mr. President, could we have 40 minutes then on the bill?

Mr. JEFFORDS. I have no objection to the Senator from Iowa being recognized as in morning business for a period of 10 minutes after the vote.

Mr. HARKIN. I understand that after the vote on this bill, the pending bill is the fast-track bill.

The PRESIDING OFFICER. The Senator is correct.

Mr. HARKIN. I ask unanimous consent that after disposition of this bill, the Senator from Iowa be recognized to speak on the fast-track bill. That is all.

The PRESIDING OFFICER. Is there objection to the request?

Mr. JEFFORDS. It would have to be in morning business.

Mr. HARKIN. I don't understand why it has to be in morning business.

Mr. JEFFORDS. It is my understanding from the majority leader that the 10 minutes the Senator is requesting should occur as in morning business. That is all I can tell you.

Mr. KENNEDY. If the Senator would be recognized for 10 minutes—

Mr. JEFFORDS. I believe the Senator would be recognized for 10 minutes, but it would be in morning business.

Mr. HARKIN. I want to ask unanimous consent that the Senator from Iowa be recognized for up to 20 minutes after the disposition of this bill.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request?

Mr. JEFFORDS. Objection. I object.

Mr. HARKIN. Then I will object to that unanimous-consent request.

The PRESIDING OFFICER. Objection is heard.

Mr. JEFFORDS. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Is there objection? Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the Senate now turn to the conference report to accompany the FDA bill, and the conference report be considered as having

been read, and that there be 40 minutes of debate equally divided, and that following the conclusion or yielding back of time, the Senate proceed to a vote for adoption of the conference report, all without further action or debate.

The PRESIDING OFFICER. Is there objection?

Several Senators addressed the Chair.

Mr. HARKIN. Reserving the right to object.

The PRESIDING OFFICER. The Senator from Rhode Island.

Mr. REED. Reserving the right to object, I don't know what I did, but a few minutes ago I had 5 minutes. There wasn't 5 minutes—

Mr. JEFFORDS. Then I will amend it to ask unanimous consent to add an additional 5 minutes for the Senator from Rhode Island, Senator REED.

Mr. REED. I thank the Senator.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request?

Mr. HARKIN. Reserving the right to object, I ask unanimous consent to amend that unanimous consent so the Senator from Iowa would be allowed 20 minutes in morning business after the disposition of it.

The PRESIDING OFFICER. Is there objection to the unanimous-consent request by the Senator from Iowa?

The PRESIDING OFFICER. Without objection, the entire unanimous-consent request is agreed to.

#### FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997—CONFERENCE REPORT

Mr. JEFFORDS. Mr. President, I submit a report of the committee of conference on the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, and ask for its immediate consideration.

The PRESIDING OFFICER. The report will be stated.

The legislative clerk read as follows:

The committee on conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830), have agreed to recommend and do recommend to their respective Houses this report, signed by all of the conferees.

The Senate proceeded to consider the conference report.

(The conference report is printed in the House proceedings of the RECORD of November 9, 1997.)

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, before us is the conference report on S. 830, the Food and Drug Administration Modernization Act. This is really an excellent moment to bring this up and consider what has been accomplished.

This bill represents the first major reform of the Food and Drug Administration in some 30 years. For our committee, it is the second major reform

that we have accomplished this session, the first one being special education, which was the first major reform for that program in some 20 years.

I am very pleased to be able to say to my colleagues that the FDA measure embodies the objectives we originally sought to accomplish.

This legislation achieves two important goals.

First, it helps the FDA to get medicine and medical devices to patients and doctors sooner and safer.

And, second, it will extend and improve the Prescription Drug User Fee Act, commonly known as PDUFA.

I am pleased to report that the conference report has the unanimous support of the conferees. It deserves the unanimous support of this body as well.

The conference report is the culmination of 3 years of hard work by dozens of Senators. It offers the most substantial reform of the Food, Drug and Cosmetic Act in decades and will have a positive impact on the lives of millions of Americans for decades to come.

Think how the world of medicine has changed over the past two or three decades. The law that governs much of that world, and nearly \$1 of every \$3 spent by consumers, must change and adapt as well.

The measure makes scores of changes in the law that ensures the safety of the food we eat, of the drugs we use to fight disease, and the medical devices we use to improve the health of Americans. It will help patients gain access to new therapies sooner without weakening either safety requirements or the authority of the FDA. It gives the agency needed tools and resources to manage an increasing workload more efficiently. In addition, it contributes to our maintaining America's technological leadership in producing pharmaceuticals and medical devices.

Achieving these reforms is a win-win situation for consumers, for the FDA, and for manufacturers. It is a win for patients and consumers, who will gain access to previously unavailable information and obtain better therapy sooner. It is a win for the FDA, which will receive new, sorely needed resources and streamlining and modernization of bureaucratic processes that have not changed in decades. And it is a win for the manufacturers, who will have a certainty that the review and approval processes applied to their innovative products will be applied in a collaborative and consistent manner.

About 10 months ago, Mr. President, we embarked anew on an effort that some characterized as foolish—an effort to modernize the regulatory processes of the FDA. Many thought it could not be done. Some urged we merely extend PDUFA or we tackle only a few issues related to drug regulation and leave the comprehensive modernization to another day.

I am glad we did not choose either of these paths. Instead, we chose to forge

a bill with broad, bipartisan support, one that took a broad view of the changes needed at the FDA.

In that regard, I particularly want to acknowledge the Democratic members of the Labor Committee, and especially Senators DODD, MIKULSKI, WELLSTONE, and MURRAY. They have made countless contributions to this legislation, large and small. Their tireless support has been critical in our success.

This measure is the result of the process to consult with individuals of all points of view and to benefit from the expertise needed to craft legislation on this complex issue. Patients, physicians, consumer groups, the FDA, and the manufacturers of medical devices and pharmaceuticals all contributed to this effort through their participation in hearings and in discussions with the staffs.

This effort was parallel to that of our colleagues in the House of Representatives, which, under the outstanding leadership of Chairman BLILEY, also produced a strong bipartisan bill with overwhelming support. The collaboration and consensus building has continued right up to the present, and the quality of this conference report we are considering today reflects that process.

Mr. President, we would not be here today if it were not for the effort of my predecessor as the chair of the Labor and Human Resources Committee, Senator Kassebaum. Her efforts to advance reform in the last Congress paved the way for our work here today. We owe her an enormous debt.

This year, there have been many Members in both Chambers who have contributed to this effort. Foremost among them has been Senator COATS. The list of provisions of this bill that bear his imprint is far too long to recite. But, as an example, the third-party review provision has been developed under his leadership, and he has played an important role in advancing FDA modernization throughout this process.

Senator GREGG is to be commended for his proposals to streamline the FDA process for consideration of health claims based on Federal research and his amendments to establish uniformity for the over-the-counter, OTC, drugs and cosmetics. Senator McCONNELL also suggested improvements in the regulation of food.

I am especially grateful to Dr. FRIST. He and Senator MACK led the way to compromise on the issue of the dissemination of medical information to health professionals, an important advance forward.

Senator DEWINE, joined by Senator DODD, offered an important amendment to establish incentives for the conduct of research into pediatric uses for existing and new drugs, a needed change. The bill was improved by Senator HUTCHINSON's amendment to establish a rational framework for pharmacy compounding, which respects the State regulation of pharmacy while allowing an appropriate role for the FDA. And

Senator HARKIN has made many contributions to this legislation.

Finally, the ranking minority member, Senator KENNEDY, has played an important role in bringing this conference report to the floor in a manner that draws support from all quarters.

In the House, Chairman BLILEY and Congressmen DINGELL, BURR, BURTON, GREENWOOD and WHITFIELD have contributed immense energy and leadership in reaching this agreement.

Mr. President, it has been a remarkable year, crowned by a remarkable, bipartisan achievement. And I thank my colleagues for their support.

Mr. President, I yield the floor and reserve my time.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, we have waited a very considerable time for this moment this afternoon in the U.S. Senate as well as action in the House of Representatives and, hopefully, the President's signature in the next few days on a matter of very significant importance to the issues of quality health for the American people.

It has been a very considerable process that we have followed over a number of years to get to this point.

I congratulate the chairman of our committee, Senator JEFFORDS, for his leadership all along this long and difficult passage, because I think without his perseverance, without his knowledge and awareness and his strong commitment on this issue, we would not have this important legislation available for the Senate and for the American people.

Mr. President, one could wonder why it has taken so much time. But we have a natural tension between bringing new innovation and creativity and breakthroughs in the areas of pharmaceutical drugs and medical devices to the market and, on the other hand, protecting the public by approving only safe and efficacious products. We have well-intentioned, brilliant medical researchers in our country who are absolutely convinced that their particular product can provide life-saving opportunities for our fellow citizens, members of our families, who are suffering extraordinary illness. And we have brilliant researchers at FDA that examine scientific information and clinical studies and believe that a very significant potential danger is out there for those who might use a particular pharmaceutical or medical device. Achieving a balance between these two concerns is a difficult task.

The one who has really balanced these conflicting views has been our chairman, Senator JEFFORDS, working diligently with other members of the committee, Democrats as well as Republicans, over a long period of time.

I am convinced that as a result of this legislation the health of the American people will be enhanced through faster availability to pharmaceutical drugs and medical devices while maintaining important protections for the

American people. I join in supporting this landmark FDA conference report.

This is a very important piece of legislation. I think in many respects this will be one of the most important pieces of legislation of this year, and possibly of this Congress.

Mr. President, I want to commend Chairman BLILEY, JOHN DINGELL, as well as Chairman BILIRAKIS, SHERROD BROWN and other members of the House committee for their bipartisan work. We had a good conference where Members were knowledgeable and very committed in terms of finding common ground. I believe as a result of this conference we have an even stronger bill than was passed earlier.

In addition, I commend the Patients' Coalition and Public Citizen, who worked to assure that the needs of patients were fully and fairly considered in the legislation. I appreciate the assistance of the Massachusetts biotechnology and medical device industries, who provided me with valuable insight into these complex issues and their concerns.

I also commend Secretary Shalala, the dedicated men and women at the FDA, and the Clinton administration for their skillful and impressive role in developing so many aspects of these needed reforms.

The most important part of the bill is the extension of the Prescription Drug User Fee Act (PDUFA) which was originally enacted in 1992. PDUFA is one of the most important FDA reform measures ever enacted. It provides funds for FDA to hire hundreds of new reviewers who, in turn, are able to expedite the review and approval of pharmaceutical products. A critical element of PDUFA's success was the establishment of measurable performance targets, which was negotiated between the industry and the FDA.

Under the PDUFA provisions in this bill, in addition to moving products through the regulatory process more quickly, the FDA and industry will also establish a cooperative working relationship and shorten drug and device development times, which now represent the most significant delay in bringing new products to market.

In addition, the bill includes a number of other constructive provisions to enhance cooperation between industry and the FDA to improve regulatory procedures.

I am particularly gratified that the bill includes broader use of fast-track drug approval. The streamlined accessibility procedure now available primarily to cancer or AIDS will be available for drug treatments for patients with all life-threatening diseases.

The bill provides for expanded access to drugs still under investigation for patients who have no other alternatives. The compromise combines protections for patients with expanded access to new investigational therapies, without exposing patients to unreasonable risks.

The bill includes a new program to provide access for patients to informa-

tion about clinical trials for serious or life-threatening diseases.

It provides incentives for research on pediatric applications of approved drugs and for development of new antibiotics to deal with emerging, drug-resistant strains of disease.

It requires companies to give patients advance notification of discontinuance of important products. And in that connection, I am disappointed that we were not able to address the issue of assuring that asthma patients and others will not be put at risk by any abrupt discontinuance of inhalers containing CFCs. I have been informed by FDA that no notice of proposed rulemaking will be issued before this summer, which will give Congress plenty of time to return to this question, if necessary.

Mr. President, the current legislation is an improvement over the bill approved by the Labor Committee earlier this year—that bill included a number of provisions that as originally proposed could have jeopardized public health.

The original bill provided a pilot program for third-party review under which private third parties, certified by the Food and Drug Administration but selected and paid by the manufacturer, would have reviewed the safety and effectiveness of medical devices to determine whether or not they could be sold.

The original proposal would have included many of the most complex and risky devices, such as digital mammography machines, and a host of other devices to detect and treat cancer and other dread diseases.

Under the final bill, these devices may not be included in the pilot program.

The original bill required the Food and Drug Administration to approve devices for marketing even if the Food and Drug Administration knew defects in the manufacturing process would make the devices unsafe or ineffective. The final legislation eliminates this requirement.

The original bill would have prevented the Food and Drug Administration from looking behind the label proposed by a device manufacturer seeking approval of a product, even if the product was false or misleading. The final legislation assures that the Food and Drug Administration will be able to require full and complete information for physicians and consumers on any potential use of the device, not just the one claimed on the label submitted with the application for approval.

And the final legislation preserves the State authority to regulate cosmetics, an area of significant potential hazard to consumers.

The legislation includes an important compromise on information on off-label use of drugs. This compromise will allow companies to circulate reputable journal articles about off-label use of drugs but will ultimately en-

hance the public health and safety because the FDA will be given the opportunity to review, comment on, and approve articles which the companies will circulate. The compromise also requires companies to undertake studies on the safety of their drugs for the specific off-label use and submit applications to the FDA for approval of their drugs for these uses within 3 years. Currently, too many off-label uses of drugs have never been reviewed for safety and effectiveness.

The bill assures the Food and Drug Administration will continue to conduct appropriate environmental impact statements, rather than be exempted from the standards that apply to every other governmental agency.

The compromise included in the bill assures the Nutrition Labeling Act is not undercut or weakened, and any health claims by food manufacturers have to be substantiated.

The legislation maintains existing standards for approval of supplemental use of drugs while streamlining the process by which they can be approved.

In summary, the current legislation is a vast improvement over the bill approved by our committee earlier this year. As a result of extensive discussion since then, including the 3 weeks of debate in the full Senate and our subsequent negotiations with the House, I believe every one of these problem issues has been resolved satisfactorily.

The bill we enact will get safe and effective products to market while assuring the Food and Drug Administration will have the tools it needs for public health. It is a landmark achievement. I urge all of my colleagues to support it.

Mr. JEFFORDS. Mr. President, I yield 4 minutes to the Senator from Tennessee.

Mr. KERRY. Mr. President, my understanding is when this business is completed that Senator HARKIN has unanimous consent for 20 minutes, and I ask unanimous consent, following Senator HARKIN, I be permitted to speak in morning business for 20 minutes.

The PRESIDING OFFICER (Mr. HAGEL). Without objection, it is so ordered.

Mr. COATS. Reserving the right to object, I don't intend to object, but I know there is an effort underway to try and bring the omnibus appropriations bill forward and I know a lot of Members are waiting around so they can take that vote. In fact, I was discussing that.

This isn't my call, but I ask the Senator if he could withhold until we can get some understanding of when that vote might be. It might be that it won't come before the Senator's 20 minutes, but if we add time here, 20 minutes there, and an additional 20 minutes, it could delay past the time when they now have commitments. I want to make sure we check that out.

Mr. KERRY. If I could allow my order to stand, I would be sensitive to



the need for a vote, and if need be, I will respond.

Mr. COATS. I accept that, and withdraw my objection.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senator from Tennessee is recognized.

Mr. FRIST. Mr. President, 3 years of hard work, which was begun by Senator Nancy Kassebaum, have resulted in the passage of the conference report to the Food and Drug Administration Modernization Act of 1997 in the Senate today. This legislation represents the first major, comprehensive reform effort since the initial amendments outlining regulation for drugs in 1962 and for medical devices in 1976. This major reform will help improve the FDA by strengthening its efficiency, accountability, and its ability to safeguard the public health.

There are several provisions contained in this bill that constitute significant reform and improvements to increase the efficiency of product review. For example, this legislation gives FDA authority to increase its access to scientific and technical expertise outside the Agency by allowing interagency collaboration with Federal agencies such as the NIH and CDC, and with the National Academy of Sciences. Also, the bill gives FDA the explicit authority to contract with outside reviewers and expand its current third party medical device review pilot program.

To help alleviate the confusion and frustration that many applicants feel when working with the FDA, the bill will require the FDA to codify evidence requirements for new drug and medical device application submissions and encourages improved communication between the agency and industry. And after 60 years, the FDA will be made more accountable by giving it a mission statement and requiring the FDA to develop a plan of action to meet its requirements under law. The bill will also reauthorize for 5 years the Prescription Drug User Fee Act, known as PDUFA, which has been tremendously successful in improving and speeding the review of much needed pharmaceutical products.

Most importantly, the bill Congress sends to the President will help patients. Individuals with a serious life-threatening disease or condition will have access to a new clinical trial database providing information on investigational therapies. Patients will benefit from the expansion of the fast-track drug approval process for new drugs intended for the treatment of serious or life-threatening conditions built on the existing program for AIDS and cancer drugs. And, patients that have no other alternative but to try an unapproved investigational product will have access to investigational therapies and medical devices.

The bill also includes a provision that will allow reprints of scientifically, peer-reviewed medical journal

articles and medical textbooks about off-label uses of FDA-approved drugs and devices to be shared with physicians and other health care practitioners. This provision will help get life-saving information to doctors, so they can be better informed when making decisions about how to treat their patients.

As a physician, I have used off-label uses to treat my patients in the past and understand its tremendous importance to the patient. Over 90 percent of treatments for cancer patients are off-label and the American Medical Association has estimated that between 40 percent and 60 percent of all prescriptions are for off-label uses of prescription drugs. I would like to acknowledge the tremendous work on this provision during the last few years by my friend, Senator CONNIE MACK and Mark Smith of his staff.

There are a number of people who worked hard to insure passage of this reform effort. I would like to thank Senator JEFFORDS, the chairman of the Labor and Human Resources Committee, for leading the bipartisan effort on FDA Reform in the Senate. I also acknowledge the leadership of Senator COATS, who has done significant work on provisions affecting medical devices in the bill. I also thank Senators GREGG, DEWINE, DODD, MILKULSKI, KENNEDY and HARKIN and their staffs for their hard work in conference. I would like to thank our House colleagues and their staffs who worked with us in conference and I especially recognize the able leadership of the chairman of the House Commerce Committee Representative TOM BLILEY and the ranking member JOHN DINGELL. I would also like to acknowledge and thank Secretary Donna Shalala and the FDA for working with us to help modernize and improve the FDA.

In particular, I would like to thank Jay Hawkins, Mark Powden, and Sean Donahue of Senator JEFFORDS' staff, Vince Ventimiglia of Senator COATS' staff, and Kimberly Spaulding of Senator GREGG's staff who were critical to the development of the bill. I thank them for their dedication and tireless effort on this important bill.

I especially want to thank the tireless work and outstanding leadership of Sue Ramthun, my staff director for health affairs, who has been so instrumental in passage of this bill.

I believe we have made a step in the right direction that will improve patient care and that this bill begins the debate on the long-term investment necessary to move the agency forward in areas such as regulatory research, professional development, and collaborative efforts between Government and academia, and I hope to continue working with my colleagues in a bipartisan manner to further improve the FDA in the following years.

Mr. KENNEDY. I yield 2 minutes to the Senator from Maryland.

Ms. MILKULSKI. Mr. President, I am so happy this day has finally come, in

which the U.S. Senate, and I believe the House, will pass a conference report to modernize the Food and Drug Administration and to bring it into a 21st century framework.

I want to thank Senator JEFFORDS for the patient leadership he has provided in moving this bill, and a special thanks for the collegiality of his staff in working with mine. I also would like to acknowledge the special role that Senator COATS has played. I have enjoyed working with him these last 3 years. We will miss him here as he undertakes next year a new life in encouraging faith-based community groups to become more involved. I think in this bipartisan collegial exchange we have come up with an outstanding bill that is going to save lives, save jobs in the United States of America, give us a product to export around the world that is translingual, transcultural, but certainly helps our people and at the same time puts patients first.

I want to particularly thank my own staff, Lynne Lawrence, for the active work she has done, and Roberta Haeberle and Kerry O'Toole in the excellent backup they have provided.

Why do I like this bill? First of all, we reauthorize the Prescription Drug User Fee Act. What this will mean is we will be able to have 600 reviewers who will be able to work at the Food and Drug Administration making sure that we cut the review time, streamline the process, be able to move drugs, biologics and devices for clinical practice in a more expedited fashion, and at the same time be able to protect safety and efficacy. We do protect safety and efficacy while we move along at a quicker step with more people.

A reauthorization of PDUFA gives us the right people and now we have the right legislative framework to do it. One of the important aspects of this legislation is the streamlining process, and yet at the same time maintaining safety and efficacy upon the approval process so more and more clinical things will be able to go into clinical practice.

I am delighted that this day has finally arrived. It is a great day for patients and physicians. They will get new medical products in a more timely and efficient manner. It is a great day for American business. They won't have to go through unnecessary regulatory hoops to get these new products on the market.

This legislation, carefully crafted between the House and Senate, represents a solid, bipartisan effort. We could not have reached this point without the incredible dedication and persistence of the chairman of the Labor Committee, Mr. JEFFORDS. I thank him for his heartfelt devotion to this bill, and for never giving up. I also thank his staff, Jay Hawkins, Sean Donahue, and Mark Powden for all their hard work.

Let me also acknowledge the tremendous contributions of our ranking

member, Mr. KENNEDY. There is no doubt this is a better bill because of his efforts. I also want to acknowledge the hard work of our counterparts in the House, the chairman of the Commerce Committee, Mr. BLILEY and the ranking member, Mr. DINGELL. Many thanks also go to the fine staff of the Commerce Committee for their excellent work.

Mr. President, I have worked on FDA reform for a number of years. When I was a Member of the House of Representatives, we embarked, on a bipartisan basis, to ensure consumer protection and to prevent dumping drugs that did not meet our standards on Third World countries.

Coming to the Senate, I joined with my colleague from Massachusetts, Mr. KENNEDY, and the Senator from Utah, Mr. HATCH, in fashioning the Prescription Drug User Fee Act (PDUFA). PDUFA has enabled FDA to hire more people to examine products that were being presented for evaluation and get them to patients more quickly.

The leadership of KENNEDY-HATCH on PDUFA has not only stood the test of time, it has shown that we can expedite the drug approval process while maintaining safety and efficacy. I am so pleased that this successful legislation will be reauthorized for 5 years.

But while PDUFA has made a huge difference, it became clear PDUFA was not enough. More staff operating in an outdated regulatory framework, without a clear legislative framework, was deficient.

That is when we began to consult with experts in public health, particularly those involved in drugs and biologics. While we were considering all this, the world of science was changing. We experienced a revolution in biology. We went from a smokestack economy to a cyberspace economy. We went from basic discoveries in science from the field of chemistry and physics to a whole new explosion in biology, in genetics and biologic materials.

It became clear we needed an FDA with a new legislative framework and a new culture. This is when we began to put together what we called the sensible center on FDA reform. We worked with Republicans and Democrats alike, because we certainly never want to play politics with the lives of the American people.

Senator Kassebaum chaired the committee during this initiative. We took important steps forward. I say to Senator JEFFORDS, you assumed that mantle, and you brought us to the point today where we will achieve final passage of FDA reform. I thank you for that.

What will this legislation do? Why is it so important? It streamlines and updates the regulatory process for new products. It reauthorizes the highly successful Prescription Drug User Fee Act. And it creates an FDA that rewards significant science while protecting public health.

It will mean that new lifesaving drugs and devices will get into clinical

practice more quickly. It will enable us to produce products that we can sell around the world, and through this, save lives and generate jobs.

FDA is known the world over as the gold standard for product approval. We want to maintain that high standard. At the same time, we want to make sure that FDA can enter the 21st century.

This legislation gets us there. It sets up a new legislative and regulatory framework that reflects the latest scientific advancements. The framework continues FDA's strong mission to protect public health and safety. At the same time, it sets a new goal for FDA, enhancing public health by not impeding innovation or product availability through unnecessary redtape that only delays approval.

There has been an urgency about reauthorizing PDUFA. Its authority expires at the end of September. PDUFA has enabled FDA to hire 600 new reviewers and cut review times from 29 to 17 months over the last 5 years. Acting now means that people who have been working on behalf of the American people can continue to do their jobs. We won't risk losing talented employees and slowing down the drug approval process.

Delay would have hurt dedicated employees, but more importantly, it would have hurt patients. Patients benefit most from this legislation. Safe and effective new medicines will be getting to patients quicker.

We're not only extending PDUFA; we're improving it. Currently, PDUFA only addresses the review phase of the approval process. Our legislation expands PDUFA to streamline the early drug development phase as well.

Instead of a carload of paper—stacks and stacks of material—being deposited at the FDA's front door, companies will be able to make electronic submissions. This not only reduces paperwork, but actually provides a more agile way for scientific reviewers to get through the data.

Updating the approval process for biotech is another critical component of this bill. Biotech is one of the fastest growing industries in our country. There are 143 biotech companies like that in my own State of Maryland. They are working on AIDS, Alzheimer's, breast and ovarian cancer, and other life-threatening infections such as whooping cough.

The job of FDA is to make sure that safe and effective products get to patients. Our job as Members of Congress is to fund scientific research and to provide FDA the regulatory and legislative frameworks to evaluate new products and make them available to doctors and patients.

This is why I fought so hard for this. This is exactly why I fought for this. My dear father died of Alzheimer's, and it did not matter that I was a U.S. Senator. I watched my father die one brain cell at a time, and it did not matter what my job was.

My father was a modest man. He did not want a fancy tombstone or a lot of other things, but I vowed I would do all I can for research in this and to help other people along these lines.

Every one of us has faced some type of tragedy in our lives where we looked to the American medical and pharmaceutical, biological, and device community to help us.

When my mother had one of her last terrible heart attacks that was leading rapidly to a stroke—there was a new drug that is so sophisticated that it must be administered very quickly. You need informed consent because even though it is approved, it is so dramatic that it thins the blood almost to the hemophilia level. I gave that approval because my mother was not conscious enough to do it.

Guess what? That new drug approved by FDA, developed in San Francisco, got my mother through her medical crisis with the hands-on care of the Sisters of Mercy in Baltimore at Mercy Hospital. Mother did not have a stroke because we could avoid the clotting that would have precipitated it.

Thanks to the grace of God and the ingenuity of American medicine, we had my mother with us 100 more days in a way that she could function at home, have conversations with us and her grandchildren.

Do you think I am not for FDA? You think I am not for safety? You think I am not for efficacy? You bet I am. And this is what this is all about. It is not a battle of wills. It is not a battle over this line item or that line item. It is really a battle to make sure that the American people have from their physicians and clinical practitioners the best devices and products to be able to save lives. That's why I'm so pleased that we were able to achieve a bipartisan bill.

So, Mr. President, I thank you for the time. If I seem a little emotional about it, you bet I am. I love FDA. I am really proud they are in my State. I thank God for the ingenuity of the American medical community. And that is why I am so pleased we will be voting on the conference report today.

All of us are happy that this bill will finally pass.

Mr. JEFFORDS. Mr. President, I yield Senator COATS 4 minutes. He is a man whose tenaciousness and ability have made this a better bill.

The PRESIDING OFFICER. The Senator from Indiana is recognized for 4 minutes.

Mr. COATS. Mr. President, as the Senator from Vermont has said, this is the first reform in 30 years at FDA. Obviously, a lot has changed in the industry. New drugs and new devices, new methods of bringing life-saving and health-improving benefits to the American people, and the people of the world. I think it is remarkable, particularly given the fact that it has been nearly 2 1/2, 3 years now that we have been specifically working on this legislation in the committee, through a

number of hearings, through a considerable, lengthy, and complex committee consideration, extensive floor debate. There were very difficult procedural hurdles to overcome and a difficult conference. We now arrive at this point with a bill that, very shortly, will be passed. This has only been done with a bipartisan effort.

I want to return the compliment to the Senator from Maryland. I thank her for that. I am not sure that everyone is going to miss me around this place, given my role in this bill, in trying to bring it forward. But I thank her for her kind words. Senators DODD, MIKULSKI, HARKIN, and WELLSTONE joined Republicans in the committee to produce a bipartisan piece of legislation, and they supported us on the floor. I thank Senator JEFFORDS and his leadership, and Senator GREGG, Senator FRIST, Senator DEWINE, and others on the Republican side, who contributed to the effort in moving the bill forward.

I would be remiss not to acknowledge the extraordinary work of so many staff people that helped to move this forward.

I thank my chief of staff, Sharon Soderstrom, and particularly Vince Ventimiglia, someone whose tireless efforts and thorough knowledge of the issues at hand, and at whose persistence we continued through all of the obstacles placed in the way of this legislation, and it was all accomplished in a manner of courtesy and respect, which is, unfortunately, all too rare around this place. He is an exceptional person. I don't believe we would be here without his efforts—even though he is not here right now; he is probably digging through the bill to make sure all the t's are crossed and the i's are dotted. He was exceptional in this whole effort.

This bill provides help to the Food and Drug Administration, who did not have the capacity nor, I believe, in the past, the managerial leadership that allowed FDA to keep pace with the marvelous breakthroughs we have had in the pharmaceutical and medical device area, which brings life-saving benefits and health-improving benefits to people. Six-hundred additional people, paid for by the industry in a tax against them to reauthorize PDUFA, will help speed up the drug approval process.

Now, for the first time, we give assistance to FDA on medical devices because we have a procedure where outside parties can, with FDA certification, approval and oversight, review medical device applications. This is going to provide for the medical device section what PDUFA provided for the drug section. This was a very critical part of the legislation, and I am pleased that it was retained in our efforts.

We are here and it is a victory for the American people. It took a lot of effort by a lot of people. It is a testament to the persistence of many, some of whom

are speaking here on the floor today. I am proud to play a role in this effort because I believe we are addressing some fundamental concerns, going to the very health and safety and very lives of the American people and people throughout the world. Mr. President, it is with that, I yield whatever remaining time I have.

Mr. KENNEDY. Mr. President, I will yield 5 minutes to the Senator from Rhode Island, but first I yield myself 15 seconds.

I want to give the assurance to my friend and colleague from Indiana, as one that didn't always see eye to eye with the good Senator on some of these issues, I pay tribute to him for the strength of his commitment and the power of his logic and argument, and the passion which he has demonstrated out here.

I have enjoyed his friendship and have always valued the opportunity to exchange ideas with him.

Mr. COATS. I thank the Senator. We have had some interesting exchanges of ideas.

Mr. REED. Mr. President, I believe I have 5 minutes.

The PRESIDING OFFICER. The Senator is correct.

Mr. REED. Mr. President, I rise today in support of the conference report on S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997. This is an important bill with serious implications for the protection of the health of the American people. Although I did not support this bill when it was first considered on the floor of the Senate, I am pleased that significant changes have been made and that this final version of the legislation is worthy of support.

This FDA reform bill is the result of ongoing negotiations both prior to and subsequent to the Labor Committee's markup of the bill. Through this process, a number of provisions that seriously threatened public health and safety were dropped or otherwise resolved. I am particularly pleased that improvements made include important protections to the third party review process. Significant changes and additions also include provisions regarding health claims for food products, health care economic claims, a notice of discontinuance when a sole manufacturer stops producing a drug, and a range of other items.

The original Senate-passed bill contained a provision regarding the FDA device approval process that posed a serious threat to public health. In effect, the Senate-passed bill would have limited the FDS's current authority to ask device manufacturers for safety data. It would have prohibited the FDA from considering how a new device could be used if the manufacturer has not included that use in the proposed labeling. As a general matter, the FDA does not consider uses that the manufacturer has not included in its proposed labeling. However, there are instances when the label does not tell the whole

story. It is these instances—when the label is false or misleading—that my and Senator KENNEDY's amendment addressed.

I was not alone in my concern about this issue. Indeed, this provision was also identified as worthy of a veto threat by the administration. The Secretary of the Department of Health and Human Services said on numerous occasions that if this provision were not changed, that she and other top Presidential advisers would recommend that President Clinton veto this bill.

By accepting the House language on this device labeling issue, the conferees have struck a reasonable compromise that will give the FDA the authority it needs to ensure that medical devices are safe and effective. In this case, the legislative process has worked, and worked well. I commend the conference committee for the sensible compromise they reached on this important issue.

The FDA is responsible for assuring that the Nation's food supply is pure and healthy and to provide a guarantee that drugs and devices are safe and effective. The FDA has an immense impact on the lives of all Americans. Indeed, the FDA's mandate requires it to regulate over one-third of our Nation's products. Few Government agencies provide this kind of important protection for the American people. On a daily basis, the FDA faces the delicate balance between ensuring that patients have swift access to new drugs and devices while guaranteeing that those new products are safe and effective.

The bill we are considering today contains many positive elements. It reauthorizes the important Prescription Drug User Fee Act, one of the most effective regulatory reforms ever enacted. The legislation also includes a number of provisions that will improve and streamline the regulation of prescription drugs, biologic products, and medical devices. I believe that these important reforms to the operation of the Food and Drug Administration will increase its efficiency and speed the delivery of important new medical treatments to patients.

One of the most important elements of this legislation is the aforementioned reauthorization of the Prescription Drug User Fee Act, often referred to as PDUFA. PDUFA established an important partnership between the agency and the industry, and has successfully streamlined the drug approval process.

I am pleased that this bill will provide expedited access to investigational therapies. This provision builds on current FDA programs related to AIDS and cancer drugs. Another important element will allow the designation of some drugs as "fast-track" medications, thus facilitating development and expediting approval of new treatments of serious or life-threatening conditions. The bill will also require the Secretary of the Department of

Health and Human Services to establish a data base on the status of clinical trials relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. Patients have long needed access to such information, and I am pleased that this bill provides a mechanism to grant it.

I am also pleased that this bill contains my amendment requiring that within 18 months of the date of enactment, the FDA must issue regulations for sunburn prevention and treatment products. In August 1978, the FDA published an advance notice of proposed rulemaking to establish a monograph for over-the-counter sunscreen drug products. To date—almost 20 years later—while progress has been made, this rule has not been made final.

Sunburn prevention and treatment products can go far to help prevent sun exposure related to skin cancer. The facts on skin cancer are compelling: one person an hour dies of malignant melanoma; half of all new cancers are skin cancers; one million Americans will develop skin cancer this year, making it nearly as common as all other types of cancer combined.

The Food and Drug Administration has a key role in our response to this skin cancer epidemic through the regulation of safe and effective sunburn prevention products that are vital to avoiding skin damage from the sun's rays.

Mr. President, I am pleased that this compromise is a bill that I can support. I look forward to working with my colleagues to oversee the implementation of this important legislation and to ensure that its provisions streamline FDA processes while also protecting the public health of the American people.

I compliment Chairman JEFFORDS, Senator KENNEDY, and many other colleagues in both the Senate and the House of Representatives who have worked hard on this bill together to eliminate many other troublesome provisions in the bill as originally introduced.

Mr. President, again, I support the conference report on S. 830, the FDA reform bill. The challenge throughout this process has been to balance a more efficient, streamlined, and productive FDA with their obligation to protect the public health. It has been a difficult task, but we made remarkable progress over the last several months. At the committee level, there was a serious discussion and debate. I could not support that version because at that time there were still outstanding issues which I thought could jeopardize the public health and safety.

When we reached the floor, there was another serious and productive debate about this legislation. Once again, I felt there were issues that had to be further addressed before I could support the measure. Today, happily, through the work of the conferees and colleagues on the floor today, we have

reached a point where we have legislation that both provides for a streamlined, productive, and efficient FDA, and continues to give FDA the authority to protect the public health.

With specific regard to the debate on the floor, there was one major issue that I felt was very important, and that was to allow the FDA to have the authority to carefully review medical devices that may be used by the public. The legislation at that time circumscribed significantly the ability of the FDA to look beyond the label, look beyond the listed use by the manufacturer, to contemplate possible other uses that may take place when the product is in the stream of commerce. Fortunately, through the work of the conferees, this situation has been resolved.

Indeed, on the floor I offered an amendment with Senator KENNEDY. It did not pass, but I think that effort helped spur a concentrated effort during the conference to develop a legislative formula to give the FDA the power to regulate these devices appropriately.

We have many, many things to be thankful for in this bill. One issue I would like to address, also, which does not rise up, in some respects, to the major reforms, PDUFA or these issues, but it is critically important; that is, the issue of protecting the public with respect to sunscreen products and sunburn products. I am pleased to note that the FDA has been directed to promulgate regulations within 18 months with respect to these products which are sold to the public to protect them from the Sun. This might seem like an innocent product, but, in fact, we are seeing a remarkable growth in incidence of skin cancer throughout the United States. One person an hour dies of malignant melanoma, skin cancer. Half of all the new cancers developing are skin cancer. One million Americans will develop skin cancer this year alone. So we have to begin to focus our attention on those products which are advertised to protect the American public.

Once again, I think this is totally consistent with the role of the FDA. I am pleased that this provision has been included in the legislation.

Let me conclude by saying, again, I believe we have struck the vital balance between an efficient, productive FDA and their obligation, historically and statutorily, to protect the public health. We have done that through the work of Senators JEFFORDS, KENNEDY, and many others. I personally thank them and applaud them for their efforts today.

I would be remiss if I didn't also thank my staff member, Bonnie Hogue, for her help through this entire process. I yield the balance of my time.

Mr. JEFFORDS. Mr. President, I will now yield to the Senator from Utah, who has been a tremendous help over the years on FDA. In fact, I am going to give him all the rest of my time—all 3 minutes.

Mr. HATCH. Mr. President, I wanted to take this brief opportunity to commend Chairman JEFFORDS for a job well done—for producing a bill which will dramatically improve the way the Food and Drug Administration does business as we move into the 21st century.

That has been one of my top priorities during my service in the Senate. I am proud that we are having the opportunity today to vote on this historic legislation which will have so many benefits for my State of Utah.

Utah is the home to over 100 medical device manufacturers, and several pharmaceutical manufacturers as well. We also are the Nation's leading producer of dietary supplements.

The Utah Life Sciences Industries Association, the leading trade association for Utah device and drug manufacturers, has worked closely with the Congress in formulating this legislation, which will have many positive effects for Utah.

On behalf of our Utah drug and device manufacturers, let me thank you Chairman JEFFORDS, and our colleague in the House, Chairman TOM BLILEY, for producing a bill which has encouraged the FDA to work in a more collaborative manner and to get the job done, to get it done professionally and expeditiously, without all the bureaucratic hassles we have experienced in the past.

And on behalf of the dietary supplement manufacturers, and most importantly the 100 million or so consumers—most of whom seem to have called our offices in the last few weeks—let me thank you for making sure that the bill does not undo the Dietary Supplement Health and Education Act in any way and that dietary supplements will remain what they are, food products, not drugs.

Finally, I wish to thank all of the staff who worked literally through the night to make today's passage of the conference report for S. 830 possible. You can be proud of your work.

#### RETIREMENT OF KATHLEEN "KAY" HOLCOMBE

Mr. HATCH. Mr. President, I could not let this opportunity pass without recognizing the extraordinary contribution that Kay Holcombe has made during almost 25 years of Government service.

Kay, who currently serves as the top health staffer on my good friend Representative JOHN DINGELL's Commerce Committee staff, has worked in a variety of positions in Government, including 6 years on Capitol Hill. Unfortunately for us, she plans to retire at the end of this session—while a fantastic opportunity for her, a regrettable loss the Congress and the Nation.

I grew to know and appreciate Kay in 1984, when I was chairman of the Labor Committee and Kay joined our staff as an American Political Science Association congressional fellow. What Kay

brought to that job was considerable. She is bright, witty, an expert on any issue she studies, and, above all, a true professional who puts good policy above politics.

What I recall most vividly about Kay's period on the Labor Committee was her incredible ability to juggle lots of balls without dropping any of them. I could always count on her to get the job done, and, in fact, to do her job and the job of three others.

I believe that Kay stands out among Government employees for the common sense she brings to any position and for an ability to bring consensus to the most difficult of issues.

We are witnessing that ability today with passage of the conference report on the FDA reform bill, a bill which—quite simply—would not have been possible without Kay Holcombe.

Her work on the Dietary Supplement Health and Education Act also stands out in my mind, where Kay's knowledge and skills as a tactician helped us overcome many an impasse. And, I might add, she was, and I suspect is, the only staffer in the Capitol who understands many of the words we wrote into that act, the most memorable of which was "lyophilize".

Her background as a bench scientist at NIH, with subsequent experience in almost every one of the Public Health Service agencies, is a record of accomplishment and experience that cannot be matched on Capitol Hill.

I, for one, will miss Kay's expertise sorely. And while I am thrilled for her as she enters this challenging new period in her life, and I am saddened at our loss here in the Congress.

To Kay, her husband Frank, her daughter and son-in-law Anne and Tony, and her mother Ginny, I wish the best as the family enters a new period of life after Capitol Hill. I hope it will be happy indeed.

Mr. KENNEDY. Mr. President, how much time do I have?

The PRESIDING OFFICER. The Senator has 8 minutes 33 seconds.

Mr. KENNEDY. I yield 4 minutes 33 seconds to the Senator from Connecticut.

Mr. DODD. Mr. President, I want to begin by thanking my colleagues who have spent innumerable hours creating a bill that will bring lifesaving drugs and medical devices to the American people more quickly and efficiently, without compromising safety or effectiveness.

First, Senator JEFFORDS is to be commended for his leadership. His staff, most notably Jay Hawkins and Sean Donahue, also deserve our appreciation for their hard work and dedication to seeing this legislation enacted.

Although the process was at times a difficult one, I'm pleased to say that a spirit of bipartisanship and compromise ultimately prevailed, as evidenced by the overwhelming Senate vote of 98 to 2 in September on this bill.

I'd also like to thank my fellow Senate conferees—Senators KENNEDY,

COATS, HARKIN, GREGG, MIKULSKI, FRIST, and DEWINE for their successful efforts to negotiate a workable compromise with our colleagues in the House.

We should take pride in the legislation that has been created—the first substantial update of FDA's rules for regulating drugs and devices since the 1970's.

We should take pride in the fact that this bill will speed critical products to patients without compromising the high safety standards that Americans have come to rely on.

Mr. President, I'd like to speak for a moment about some of the positive reforms contained in this bill.

At the heart of the bill is the 5-year reauthorization of PDUFA, the Prescription Drug User Fee Act—a piece of legislation remarkable for the fact that there is unanimous agreement that it really works.

In the 5 years since this initiative was created, the fees collected under PDUFA have cut drug approval times in half. With its renewal as part of this bill, we can expect drug approval times to drop an additional 10 to 16 months.

In addition, by improving the certainty of product review process, this bill encourages U.S. companies to continue to develop and manufacture in the United States. This bill asks the FDA and industry to begin collaborating early in the approval process to prevent misunderstandings about agency expectations that ultimately could delay a needed product from reaching consumers.

This bill also establishes or expands upon several mechanisms to provide patients and other consumers with greater access to information and to lifesaving products.

For example, this bill will give individuals with lifethreatening illnesses greater access to information about ongoing clinical trials of drugs—information that may offer the only hope for those patients who have not benefited from treatments already on the market.

Based on a bill originally championed by Senators SNOWE and FEINSTEIN, I offered an amendment in committee, which I was pleased to see adopted, to expand an existing AIDS database to include clinical trials for all serious or lifethreatening diseases.

Individuals struggling with chronic and debilitating diseases should not be burdened with the daunting task of searching, without assistance, to locate studies of promising treatments. This database will provide one-stop-shopping to help those patients quickly and easily access vital information.

Mr. President, I am particularly pleased that this bill incorporates the Better Pharmaceuticals for Children Act, legislation originally introduced by our former colleague from Kansas, Senator Kassebaum, and now cosponsored by myself and Senator DEWINE.

This provision addresses the problem of the lack of information about how

drugs work on children, a problem that President Clinton recognized recently as a national crisis.

According to the American Academy of Pediatrics, only one-fifth of all drugs on the market have been tested for their safety and effectiveness in children. This legislation provides a fair and reasonable market incentive for drug companies to make the extra effort needed to test their products for use by children.

I was pleased to join Senator JEFFORDS as the first Democratic cosponsor of this bill. I would thank him again for the hard work and long hours that he and his staff have contributed.

I look forward to joining my colleagues in voting in favor of this legislation.

Let me join here, Mr. President, the chorus of praise for those who have been involved in putting this bill together. It has been a long journey and not always an easy one, but I think the final product is a good one. I commend the chairman of the committee, Senator JEFFORDS, and his staff, Jay Hawkins, Sean Donahue, Jeanne Ireland of my staff, for their hard work and dedication in seeing this process to its conclusion. We swept the Senate with an overwhelming vote of 98 to 2 on what I thought was a good bill. Our conferees worked very hard. I thank Senators KENNEDY, COATS, HARKIN, CRAIG, MIKULSKI, FRIST, and DEWINE for their successful efforts in this area as well.

This is a critically important piece of legislation that will expedite the process of getting needed medicines and devices to patients, without compromising safety or effectiveness. That was a desired goal of everybody here.

Let me, if I can, mention two or three provisions in the bill that I think are worthy of special note. One, of course, is a 5-year reauthorization of PDUFA, which is very, very important. I think it demonstrates the success of the PDUFA and how well it worked over 5 years.

Secondly, I also would like to commend our colleagues for accepting the several mechanisms to provide patients and consumers with greater access to information and to life-saving products. For example, this bill gives individuals with life-threatening illnesses greater access to information about ongoing clinical trials and drugs that could be very, very important to them and their families. By the way, Senator SNOWE and Senator FEINSTEIN deserve particular credit. It was originally their idea that we incorporated in the bill, the Better Pharmaceuticals for Children Act. Former Senator Kassebaum of Kansas originally authored that idea, Mr. President. Senator DEWINE and I included it in this bill. I think it has been improved upon in the conference. It is a very important provision that could make a huge difference for young children and their families who want to have reliable products that will become available to them.



So, Mr. President, let me conclude by again thanking all those who have been involved in this process. Passing this legislation can truly be considered one of the very fine achievements of this first session of this Congress. I look forward to its effectiveness with the American consumer.

#### APPROPRIATIONS TRIGGER

Mr. BUMPERS. Mr. President, on September 23 of this year, my colleague, Senator COCHRAN, chairman of the Appropriations Subcommittee on Agriculture, Rural Development, and Related Agencies, rose on the floor of the Senate to express objection to a provision of the FDA reform bill that would direct the appropriations subcommittee to provide established levels for salaries and expenses of the Food and Drug Administration through fiscal year 2002. If the appropriations bills did not meet those levels, referred to as trigger, the FDA would not be able to collect or use receipts authorized by the Prescription Drug User Fee Act [PDUFA]. The effect of the provision Senator COCHRAN found so troublesome would have been to place a budgetary gun to the head of the appropriations subcommittee under threat of PDUFA fees not being collected and the Nation's drug approval process placed at risk. As ranking member of the appropriations subcommittee, I shared Senator COCHRAN's concerns, but honestly hoped that the problem he highlighted would be corrected before we were faced with final passage of the conference report on FDA reform. While the conference report before us today does provide some relief in fiscal years 2001 and 2002 from the earlier Senate language, I am still disappointed that more progress was not achieved to inject a greater dose of realism into the expectations of the FDA authorization committees of the House and Senate.

I do not mean to detract from the very important work of the FDA nor to minimize the need to push ahead aggressively with drug approvals. I equally appreciate the concerns of the prescription drug industry, which will be responsible for paying the PDUFA fees, that their considerable contributions will be used to supplement, not supplant, the drug approval process. However, an unfortunate charade has been employed to suggest the language now contained in FDA reform is going to protect, in fact guarantee, increases in the level of Federal funds appropriated for FDA drug approvals. I must point out to my colleagues that the language before us does nothing to assure that very goal and I feel compelled to highlight the provision's failing.

FDA reform would require the appropriations bills for fiscal years 1999 through 2002 to provide levels for the FDA salaries and expenses account at levels no lower than the fiscal year 1997 level adjusted by the lesser of inflation based on the consumer price index or changes in growth of national domestic discretionary spending. The FDA sala-

ries and expenses account contains funding for all activities of FDA, including drug approvals, subject to an appropriation other than amounts for buildings and facilities. The FDA reform legislation contains no requirement that FDA allocate any portion of the salaries and expenses account for drug approvals. Therefore, while our appropriations subcommittee may comply with the full letter of FDA reform requirement, that act alone would provide no assurance to the drug industry that the FDA appropriation would be used as they expect. FDA certainly has other pressing budgetary demands such as the need to account for the rental space arrearage for which the General Services Administration is threatening action against FDA, and continued work on tobacco issues. FDA will also need increased attention in the area of food safety which continuing headlines, such as that appearing in the Washington Post this weekend about the more than 700 people made ill by contaminated food in southern Maryland, will no doubt place greater workload on the agency. An arbitrary appropriation trigger will produce no magic bullet aimed solely at the problem of drug approval backlogs.

Mr. President, I might have a little more understanding for the concerns of the drug industry if there was any merit to their claim that the appropriations subcommittee would not hold faith with their requests. Over the past 10 years, our subcommittee has increased new budget authority for FDA salaries and expenses from \$456,004,000 to \$857,501,000. In fact, I would like the RECORD to reflect the amounts provided in that account on a year-to-year basis since fiscal year 1988 to the present, and I ask unanimous consent the year and amounts be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

Fiscal year 1988—\$456,004,000.
Fiscal year 1989—\$487,344,000.
Fiscal year 1990—\$574,171,000.
Fiscal year 1991—\$656,519,000.
Fiscal year 1992—\$725,962,000.
Fiscal year 1993—\$746,035,000.
Fiscal year 1994—\$813,339,000.
Fiscal year 1995—\$819,971,000.
Fiscal year 1996—\$819,971,000.
Fiscal year 1997—\$819,971,000.
Fiscal year 1998—\$857,501,000.

Mr. BUMPERS. I have included this history of funding to show how the amount of appropriations for FDA salaries and expenses has increased every single year since fiscal year 1988 except for the period between fiscal year 1995 and fiscal year 1997 when the level was held at a freeze. I also want to note that the 3-year period connecting fiscal year 1995 and fiscal year 1997 was a period in which the 602(b) allocation to our subcommittee fell by 11 percent. I hope my colleagues see in this history a commitment by our subcommittee to recognize the importance of FDA's activities. Further, I hope my colleagues see that even during a time when near-

ly all other programs under our jurisdiction had to take significant reductions, FDA was held harmless. I believe this history reflects well on the commitment and good faith of our subcommittee.

An obvious result of the provision contained in FDA reform will be continuing further reductions in other programs under the jurisdiction of our subcommittee. Those programs will again have to suffer unless, in the unlikely event, we receive substantial increases in our future 602(b) allocations. There are many, many other programs for which our subcommittee is responsible that are important to people and communities all across the Nation. Our bill provides funding for all activities at the U.S. Department of Agriculture—except the Forest Service—and the Commodity Futures Trading Commission. At USDA alone, there are hundreds of programs essential to rural and urban America that will be harmed, again, if our subcommittee is expected to provide FDA, and FDA only, with inflation increases through fiscal year 2002. USDA programs have already been radically cut by our subcommittee over the past several years while, as noted above, FDA was provided substantial increases or, at least, held constant.

I understand a few other proposals were suggested, and rejected, during consideration of the FDA reform legislation. One proposal was to hold FDA to a freeze, something which we have shown we have done historically. Another proposal would have specifically protected the FDA activities for drug approvals. That approach would have better addressed the concerns I outlined above. I understand this proposal to protect FDA drug approvals was rejected due to objections from nondrug related industries concerned that FDA resources might be transferred from their own specific priority areas to drug approvals. Ironically, that is the same concern I have heard from groups fearful about what the provision in FDA reform will do to USDA and CFTC programs.

Mr. President, at times I feel there is an outright assault on the appropriations process. Too many times in recent years we have seen requirements imposed on the Appropriations Committee by other legislative and procedural vehicles that continuously impairs our ability to respond to agency needs and responsibilities to our states and the American people. Based on administration projections, the trigger mechanism contained in FDA reform would force the appropriations subcommittee to increase the FDA salaries and expense account from the current \$857 to \$876 million in fiscal year 2002. According to the President's 1998 budget, the projected request for FDA salaries and expenses for fiscal year 2002 is only \$691 million. This is a difference of nearly \$200 million, an

amount worthy of deliberate consideration by the appropriations subcommittee. Additionally, the FDA reform provision does not account for the possibility of a tobacco settlement that might replace current appropriations expenditures, consolidation of food safety functions in some agency other than FDA, or other potential changes that would affect, and possibly reduce, the budgetary requirements of FDA. Even though the provision does attach the trigger to the lesser of the consumer price index or changes in the growth of national domestic discretionary spending, there is no guarantee that any increase in overall domestic discretionary totals will be reflected in the 602(b) allocation for our subcommittee.

For the coming year, I can assure my colleagues that I will work with Senator COCHRAN and others to assess the requests of all agencies and departments that will come before our subcommittee. I strongly believe that we have been fair in our setting of priorities and that we will continue to consider the merits of all requests in order to balance the fiscal demands and resources in a manner consistent with our abilities, good judgment, and the recommendations of all Senators.

Ms. MOSELEY-BRAUN. Mr. President, I support S. 830, the conference report for the Food and Drug Administration Modernization and Accountability Act of 1997, and commend the conferees for quickly reaching agreement on compromises that will ultimately improve the FDA and improve the public's access to cutting edge medical technology.

I am also pleased that we are going to pass this important legislation before adjourning for the year. The American people will be much better off as a result of our actions here today. S. 830 is a perfect example of Congress enacting public policy that Americans both want and need.

There is no disagreement as to the caliber of the Food and Drug Administration. FDA is one of the finest regulatory agencies in the Nation and the world. However, the length of time and amount of paperwork required for FDA approval of new products may still be excessive. For many companies, particularly small and startup businesses, the FDA application process is a formidable time consuming obstacle. These barriers exist despite the recent agency improvements to their review process. In some cases, the length and complexity of the process can force companies to launch their products abroad rather than here in America. This is a troubling prospect, particularly given the increasingly competitiveness of global markets.

The FDA, like all other entities, must evolve and adapt to the changing global landscape. Traditional methods of product review are no longer efficient. Industrialized and emerging nations now participate in multilateral trade agreements aimed to reduce

trade barriers. While the U.S. continues as the world's premiere economy, our market dominance is dwindling. A recent Washington Post article indicated that our Nation was far more dominant economically following World War II, when the U.S. economy accounted for more than 25 percent of the world's output, than it is today. Evolving global markets hold untapped potential for product manufacturers. The ability to lucratively launch products abroad will bring pressure on the FDA to harmonize its regulatory policies with other international safety and performance standards. The traditional policies that have made the U.S. the "gold standard" in public health protection threaten to undermine our competitiveness. In order to maintain its status as the gold standard, the FDA must implement policies that encourage the launching of new products in this country, as opposed to Europe, and ensures that the United States maintains its technical and scientific leadership in health disciplines.

Mr. President, S. 830 strikes a delicate balance between protecting the public health, fostering global trade under multilateral agreements, ensuring swift access to new health technology for Americans, and strengthening the U.S. technical and scientific leadership.

The conference agreement reauthorizes the Prescription Drug User Fee Act (PDUFA) for an additional 5 years. PDUFA has been one of the most successful pieces of governmental reform legislation. During the 5 years since we first passed PDUFA, the average approval time for pharmaceutical products has dropped over 40 percent. The pharmaceutical and biologics industries overwhelming support reauthorization of PDUFA because they have seen tangible results from their fee payments. The American public also supports reauthorization of PDUFA because they have received access to innovative treatments in a more timely manner.

S. 830 also makes considerable progress in expediting patients' access to important new therapies and potentially life saving experimental treatments. I have long held that access to alternative medical treatments is an essential part of health care freedom of choice. Under the conference agreement, patients with fatal illnesses will no longer be denied access to potentially life-saving treatments. I am sure that each of my colleagues can recount tales of constituents who have encountered considerable bureaucratic red-tape in their efforts to access a non-FDA approved but potentially life-saving treatment. Although I have great respect for the role that the agency and its employees play in protecting consumers from unsafe and ineffective products, there is a problem when informed Americans cannot get access to desired therapies. S. 830 makes some much needed reforms to enhance that access.

Mr. President, the conference agreement includes reasonable compromises on provisions concerning medical device labeling, dissemination of information concerning drug off-label use, and regulation of device manufacturing. Ensuring that unapproved medical devices not get onto the market that clearly have a different use than the labeling indicates is a vitally important task. This issue alone was responsible for delaying approval of the Senate version of the FDA Modernization Act. I am pleased that the conferees reached an agreement to give FDA the necessary regulatory authority but not subject manufacturers to the whims of various application reviewers. FDA will be given the necessary authority to prevent fraudulent labeling as a means of achieving product approval.

Similarly, S. 830 strikes an appropriate balance between protecting the public interests and allowing manufacturers to share important off-label use information with providers. It would have been a grave mistake to either prevent the distribution of off-label use information or not allow the FDA to play a vital role in ensuring the adequacy of information being distributed by manufacturers. I know that a lot of work went into the compromise reached regarding off-label usage information and the agreement greatly benefits the American public.

Mr. President, I would also like to congratulate patients groups for their steadfast pursuit of this reform. During this year, I have met with countless numbers of my constituents who will immediately have better access to medical treatment as a result of this conference agreement. Each time we met, their message was loud and clear—pass FDA reform now. This is a resounding message that I cannot ignore.

S. 830 builds on the reforms that the FDA has already put into place over the past 5 years. The agency has taken a number of steps to streamline administrative functions and work better with industry and consumers to facilitate the availability of cutting edge medical technology. The success that FDA has achieved in reducing the time to review new drugs and get potentially life-saving therapies on the market is laudable. However, more improvements are needed and S. 830 moves another step in the right direction.

My support for S. 830 is not a complete endorsement of the bill. There are a number of important provisions absent from this legislation. I am particularly concerned that the bill does not adequately address food safety, which will certainly emerge as a major public health issue. Most of the recent criticism of the FDA has focused on the biologics and medical technology areas. Regulation of imported food products will probably be the pressing issue of the next millennium. As more imported agricultural products find their way to American tables, there

will be more pressure upon FDA to act to prevent tainted products from getting to the market. The recent problems with tainted meat and poultry highlight this need for greater focus on food safety. Hopefully, Congress can revisit the shortcomings in food safety standards next year.

Nonetheless, S. 830 is a good start down the road of FDA reform. This conference agreement is better than the bill passed by either the House or Senate and considerable better than the bill developed last year. I am happy to have a conference agreement that I can support and that I truly believe moves the country in the right direction. S. 830 is good for patients, good for the industry, and good for the Nation's global competitiveness. I hope that my colleagues will join me in supporting this important legislation.

Mr. KENNEDY. Mr. President, how much time do I have?

The PRESIDING OFFICER. The Senator has 5 minutes 48 seconds.

Mr. KENNEDY. I yield myself 5 minutes.

Mr. President, I just want to review once again, very briefly, the principal provisions in the legislation which I think are enormously constructive and positive.

First of all, building on the PDUFA record, this provision that we have enacted expands the existing program by setting additional performance targets. It puts special emphasis on expanding early cooperation and FDA and the industry, which will reduce the development time, so that the drug development process, not just the regulatory review process, can be expedited. That is very important.

There are many other positive achievements in the legislation. I am particularly gratified, as I mentioned earlier, with the broader use of the fast-track approval. The streamlined accessibility procedure now available primarily to patients with cancer or AIDS will also be available for drug treatments for patients with any other life-threatening diseases. This bill also provides for expanded access to drugs still under investigation for patients who have no other alternatives. The compromise combines protections for patients with expanded access to new investigational therapies, without exposing patients to unreasonable risks.

The bill includes a new program to provide access for patients to information about clinical trials for serious or life-threatening diseases.

It provides incentives for research on pediatric applications of approved drugs and for development of new antibiotic to deal with emerging, drug-resistant strains of diseases.

It requires companies to give patients advance notification of discontinuance of important products. And in that connection, I am disappointed that we were not able to address the issue of assuring that asthma patients and others will not be put at risk by any abrupt discontinuance of

inhalers containing CFC's. I have been informed by FDA that no notice of proposed rulemaking will be issued before this summer, which will give Congress plenty of time to return to this question, if necessary.

The bill includes many measures that will reduce unnecessary regulatory burdens and appropriately clarify its authority.

These provisions, as well as others, are extremely constructive and will be enormously helpful to the American consumer.

Mr. President, I would like to mention some of the staff who have been a crucial part of this whole process. Those members of our staff on the Labor Committee: Nick Littlefield, David Nexon, Diane Robertson, Debbie Kochevar, Pearl O'Rourke, Jim Manley, Leslie Kux, and Carrie Coberly.

Bonnie Hogue with Senator REED, Sabrina Corlette and Peter Reinecke with Senator HARKIN, Jeanne Ireland with Senator DODD, Deborah Walker with Senator BINGAMAN, Anne Grady with Senator MURRAY, Linda DeGoutis with Senator WELLSTONE, Lynne Lawrence with Senator MIKULSKI, and Anne Marie Murphy with Senator DURBIN.

With the Republicans are the following staff:

Jay Hawkins, Sean Donohue, and Mark Powden, with Senator JEFFORDS; Vince Ventimiglia with Senator COATS; Kimberly Spaulding with Senator GREGG; Sue Ramthun with Senator FRIST; and Saira Sultan with Senator DEWINE.

Also, the House staff were instrumental in the success of this conference:

Kay Holcombe, as Senator HATCH has indicated, worked with us when she worked with Senator HATCH on the committee years ago and was very constructive during this process. Howard Cohen, Rodger Currie and Eric Berger also with the Commerce Committee, and Paul Kim on Congressman WAXMAN's staff.

And I thank the FDA staff: Bill Schultz, Peggy Dotzel, and Diane Thompson.

I thank them all very much for all of their help and their involvement.

#### PRIVILEGE OF THE FLOOR

Finally, I ask unanimous consent that Tom Perez, a Justice Department detainee on the Judiciary Committee, be given floor privileges for the remainder of the session.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, how much time remains?

The PRESIDING OFFICER. One minute forty-five seconds.

Mr. KENNEDY. Mr. President, we again thank our colleagues and friends and look forward to the passage of this legislation.

If there are no other comments, I would be prepared to yield the remainder of our time.

Mr. JEFFORDS. Mr. President, I yield the remainder of my time.

The PRESIDING OFFICER. The question is on agreeing to the conference report.

The conference report was agreed to. Mr. KENNEDY. Mr. President, I move to reconsider the vote by which the conference report was agreed to.

Mr. JEFFORDS. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. JEFFORDS. Mr. President, I would like to take a moment to thank the staff who have worked to make this bill possible. In the office of Senate Legislative Counsel, Robin Bates, Elizabeth Aldridge, and Bill Baird worked tirelessly to produce countless bill drafts and amendments. I would also like to commend House Legislative Counsels David Meade and Pete Goodloe for their work on the conference report.

The staff at CRS, especially Donna Vogt, and at GAO, including Bernice Steinhart deserve thanks for their willingness to provide essential information and documents on extremely short notice.

The staff to the members of the committee contributed greatly to the success of this bill. Vince Ventimiglia with Senator COATS' staff worked closely with mine in a true partnership on all aspects of S. 830.

In addition, Kimberly Spaulding with Senator GREGG, Sue Ramthun with Senator FRIST, Saira Sultan with Senator DEWINE, and Kate Lambrew-Hull with Senator HUTCHINSON all played important roles in fashioning compromises on key provisions of this conference report, as did Dave Larson and Barry Daylin.

Similarly, three staffers for members of the minority on the committee played pivotal roles throughout the process—from the premarkup stage through the development of this conference report. Their assistance was critical to making this bill a bipartisan success.

Lynne Lawrence with Senator MIKULSKI deserves special mention in recognition of her hard work both in the last Congress and in this one on FDA reform. Following passage of this conference report, Lynne will be leaving Capitol Hill. I am extremely pleased that she will be leaving on a high note, and we all wish her the best with future pursuits. Jeanne Ireland with Senator DODD and Linda Degutis, a fellow with Senator WELLSTONE also provided invaluable assistance throughout the process.

Finally, I thank, of course, the Labor and Human Resources Committee majority and minority staffs. On the minority staff, I would like to thank Nick Littlefield and David Nexon and two minority fellows Diane Robertson and Debbie Kochever.

On my own staff, I would like to thank the majority staff director Mark Powden, Jay Hawkins, and majority fellow Sean Donohue. All have devoted substantial portions of their time over the past 10 months to this effort.

Jay Hawkins, in particular, has been key to making this conference report a reality. His tireless efforts, his unfailing good humor, and his patience have allowed this process to maintain steady forward progress to a highly successful outcome.

The round-the-clock work, particularly over the past few days, of all the staff involved in the conference is greatly appreciated.

Mr. President, I could not be happier with this moment and at this time will happily leave the floor.

Mr. HARKIN addressed the Chair.

The PRESIDING OFFICER. The Senator from Iowa.

Mr. TORRICELLI. Mr. President, will the Senator from Iowa yield?

Mr. HARKIN. I yield without losing my right to the floor for a unanimous-consent request.

Mr. TORRICELLI. Mr. President, I ask unanimous-consent that at the conclusion of the remarks of the Senator from Iowa, I be able to address the Senate for 20 minutes.

The PRESIDING OFFICER. The Senator should be aware that under a previous order the Senator from Massachusetts is to be recognized after the Senator from Iowa.

Mr. TORRICELLI. Then I will amend my unanimous-consent request that after those Senators are recognized under the unanimous-consent request that I be able to address the Senate for 20 minutes.

Mr. JEFFORDS. Reserving the right to object, I make a point of order that a quorum is not present.

Mr. HARKIN. Mr. President, I have the floor, I believe, and I yielded only to the Senator for the purpose of a question.

The PRESIDING OFFICER. The Senator from Iowa is recognized, and he has the floor.

The unanimous-consent request from the Senator from New Jersey is on the floor. Without objection, it is so ordered.

Mr. JEFFORDS. I object. I make a point of order that a quorum is not present.

Mr. HARKIN. Mr. President, I believe I have the floor. I only yielded for the purpose of a unanimous-consent request.

The PRESIDING OFFICER. The Senator from Iowa has the floor.

Mr. HARKIN. Mr. President, I will reclaim the floor in my own right and let these Senators work it out if they want to come back.

The PRESIDING OFFICER. The Senator from Iowa has the floor and is recognized for 20 minutes. He may proceed.

Mr. HARKIN. Thank you, Mr. President.

#### FAST-TRACK LEGISLATION

Mr. HARKIN. I want to speak a little about the fast-track bill that is before us and which is scheduled to be voted on in the House tonight.

I doing so, I reread the President's speech on September 10 that he gave on fast track. He gave it at the White House, I believe in the East Room.

I found some interesting remarks in the President's speech. He talked about change. He said, "As we have done throughout our history, we have taken our Nation and led the world to the edge of a new era and a new economy." He is absolutely right.

He talked about the economy, and how we are the largest producer of automobiles, agricultural exports, semiconductors, steel, and other items.

Then, closer to the end of the speech, the President said, "As we continue to expand our economy here at home by expanding our leadership in the global economy, I believe that we have an obligation to support and encourage core labor standards and environmental protections abroad."

He further said in his speech—this is the President's speech on September 10—"Our goal must be to persuade other countries to build on the prosperity that comes with trade and lift their standards up. As we move forward, we must press countries to provide the labor standards to which all workers are entitled," et cetera.

The President said in his speech that we are part of a new world economy. I would say, yes, Mr. President, we are also part of a new world community—a new world community the likes of which we have never seen because of the rapid dissemination of information, the globalization of communication, the instantaneous transmission of images and voice, transmittal of information around the globe. People living in the remotest villages of Africa, China, or Asia now know what is happening in other parts of the world. No longer is it kept from them. Increasingly the people on this planet are going to demand their human rights, their fundamental basic human rights, their individual freedoms. That is what Tiananmen Square was all about.

Yes, Mr. President, you were right. You were right, Mr. President, to say to President Jiang of China that China was on the wrong side of history at Tiananmen Square. You were right, Mr. President. But, Mr. President, to the extent that we have a trade bill before us that limits your authority to negotiate under fast track regarding exploitative child labor, that weakens the provisions dealing with child labor, then you, Mr. President, and this country are on the wrong side of history.

Those may sound like strong words, but as I have read the President's speech, and as I read the fast-track bill before us, one can only come to one conclusion. This legislation takes us in the wrong direction. It severely limits the ability of the President and our trade negotiators to address the issue of exploitative child labor in trade negotiations. That is right. This bill limits the President's authority. The 1988 bill didn't. I will explain this.

In this bill, child labor is included in a category of issues under the heading

"Regulatory Negotiations." Under this heading in the bill, negotiations under fast track on child labor may only cover—I will read it—"the lowering of, or derogation from, existing \* \* \* standards."

That is all. The language does not allow negotiations aimed at getting a country to agree to raise its child labor standards, no matter how weak or non-existent they may be.

Furthermore, the negotiations may only address cases where the other country's lowering of, or derogation from, its child labor standards is—and I will read it directly from the bill—"for the purpose of attracting investment or inhibiting United States exports."

I want to make sure my colleagues understand that.

First of all, the President may only negotiate regarding the lowering of, or derogation from, existing labor standards. He can't negotiate on strengthening them. And he may only negotiate regarding the situation where the lowering of, or derogation from, standards is done for the purpose of attracting investment or inhibiting U.S. exports.

What about the case where a country lowers or fails to enforce its child labor standards for the purpose of producing goods at lower cost so it can ship them to the United States? That situation is not mentioned in this language, so the President does not have authority to negotiate on that basis according to the terms of the bill. Allowing the use of exploitative child labor to hold the price of goods down is unfair competition, plain and simple, but a country could do that.

Exploitative child labor in foreign countries unfairly puts competing firms and workers at a disadvantage in the United States and in other countries that do not allow it. Yet, the language in this bill does not indicate that President would have the authority to address that kind of unfair competition against U.S. companies and workers in negotiations and agreements under fast track. As long as the other country is not lowering or derogating from its standards for the purpose of attracting investment or inhibiting U.S. exports, our negotiators cannot negotiate to end this unfair competition.

The bottom line is that this bill limits the President's authority to seek agreements that would curtail exploitative child labor.

It is important to clarify this point. I think people will say "HARKIN, what are you talking about? How could it limit the President's authority?"

Well, let us examine that question. Under this bill, the President actually has less authority to negotiate regarding child labor, and submit an agreement to Congress under fast-track procedures, than he had in the most recent fast-track legislation, which was contained in the Omnibus Trade and Competitiveness Act of 1988—the last bill laying out fast-track procedures that we voted on and which this Senator voted for.